AN OPEN COMPARATIVE CLINICAL EVALUATION ON "SAGANA VATHAM (CERVICAL SPONDYLOSIS)" WITH SIDDHA HERBAL FORMULATION DRUG "KURUNTHOTTI KASHAYAM"(INT), "AZHINJIL THYLAM"(EXT) AND "VARMAM THERAPY".

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled "An open comparative clinical evaluation on "sagana vatham" (Cervical spondylosis) with siddha herbal formulation drug "Kurunthotti Kashayam"(internal), "Azhinjil Thylam"(external) and "Varmam Therapy" is a bonafide and genuine research work carried out by me under the guidance of **Dr. M. MOHAMED MUSTHAFA M.D(S).,** Professor, Post Graduate Department of **Sirappu Maruthuvam**, Govt. Siddha Medical College, Arumbakkam, Chennai- 600106 and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

Date: **Signature of the Candidate**

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CERTIFICATE BY THE GUIDE

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This is to certify that the dissertation entitled "An open comparative clinical evaluation on "Sagana vatham" (Cervical spondylosis) with siddha herbal formulation drug "Kurunthotti Kashayam"(internal), "Azhinjil Thylam"(external) and " **"**Varmam Therapy**"** is a bonafide work carried out by R. Rasakumar during the year 2015-2018 under the guidance of **Dr.M.MOHAMED MUSTHAFA, M.D (S).,** Post Graduate Department of Varmam, Pura maruthuvam & Sirappu Maruthuvam, Government. Siddha Medical College, Chennai - 600 106.

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CONTENTS

INTRODUCTION

Siddha Medical system is a special, significant and scientific system, being in practice, since time immemorial. It is one of the ancient systems of medicine in the world and it is unique system which is formal among the Tamil people of South India rendering service to humanity for more than five thousand years in combating diseases and in maintaining physical and mental and spiritual health.

The father of siddha medicine is the primordial guru **Agasthiar**. There are also 18 prime siddhars who are the followers of the primordial guru, contributed their valuable knowledge and experiences in the siddha system.

Siddha means "one who is accomplished". It refers to who have achieved a high degree of physical as well as spiritual perfection or enlightenment.

"பித்தன் மருந்தால் தெளிந்து பிரகிருதி

உய்த்துஒன்று மாபோல், விழியுந்தன் கண்ணொாலி

அத்தன்மை ஆதல்போல், நந்தி அருல் தரச்

சித்தம் தெளிந்தேன் செயல்ஒழிந் தேனே"

\- திருமூலர் திருமந்திரம்

Siddha medical system consist of sixty four kinds of medicines including thirty two kinds of internal medicines and thirty two kind of external medicines. They have tremendous work on raw materials from herbal, herbo-mineral, metal and animal origin and formulated many medicines. Siddhars also played a great part with their contributions in rasavatham (alchemy), yogam, karpam, varmam, etc.,

The siddhars were also aware of several alchemical operations divided into several processes such as calcinations, distillation, fusion, separation conjunction or combination, congelation, cibation, fermentation, exaltation i.e. the action or process of refining gold, fixation i.e. bringing to the condition of being non –volatile or to the state of resisting the action of fire, purification, incineration of metals, liquefaction, extraction etc.,

Varmam is a branch of siddha system of medicine which involves a special kind of therapy based on vital points called Varma points present in the body. Varmam is an subtle energy flow circulating inside the body. The treatment methodologies are employed in the clinical practice, especially for Musculo-skeletal disorders and Neurological disorders.

Cervical spondylosis is defined as arthrosis of the posterior intervertebral joints in the cervical vertebrae.

The prevalence of cervical spondylosis is similar for both sexes, although the degree of severity is greater for males. Evidence of spondylotic change is frequently found in many asymptomatic adults, with 25% of adults under the age of 40, 50% of adults over the age of 40, and85% of adults over the age 60 showing some evidence of disc degeneration. Another study of asymptomatic adults showed significant degenerative changes at 1 or more levels in 70% of women and 95% of men at the age 65 and 60years. An increased incidence has been noted in patients who carried heavy loads on their heads and shoulders, dancers, gymnasts,etc.,

In siddha literature (Yugi Vaithiya Sinthamani) a condition called Saganavatham shall be correlated with symptoms of Cervical spondylosis.

The current treatments include administration of nonsteroidal anti-inflammatory drugs (NSAIDS), muscle relaxants, narcotics, anti-epileptic drugs, and corticosteroids, physiotherapy and so on. However there is little evidence to support the efficacy of these therapies for cervical spondylosis. The usage of NSAIDS, and steroids drugs often pose to hepatotoxicity, nephrotoxicity, and adverse drug reactions affecting gastrointestinal tract, central nervous system etc., There is no complete treatment in other system.

So the need of the hour is to search an effective drug and therapy to treat cervical spondylosis with less or no adverse effects. So i have ventured to compare the efficacy of poly herbal drug ‘Kurunthotti kashayam’(Internal) and Azhinjil thailam (External) with supporting varmam therapy for the management of saganavatham (cervical spondylosis).

AIM& OBJECTIVES

AIM:

To evaluate the therapeutic efficacy of siddha trail drugs "Kurunthotti Kashayam"(internal), "Azhinjl thailam"(external) and "Varmam therapy" on saganavatham (Cerviacl spondylosis)

OBJECTIVES:

PRIMARY OBJECTIVE:

To evaluate the therapeutic efficacy of siddha trail drugs "Kurunthotti Kashayam" (internal), "Azhinjil thailam"(external) and "Varmam therapy" on saganavatham (Cerviacal spondylosis)

SECONDARY OBJECTIVE:

- To Standardize the standard operating procedure for both siddha trail drugs. Standardization through both traditional modern analytical techniques
- Evaluation of acute and sub- acute toxicity studies for the trail drug "Kurunthotti Kashayam"
- To evaluate the pharmacological activity Anti-inflammatory and analgesic activity of the trail drug Kurunthotti Kashayam in animal model
- To evaluate the safety of the trail drug Kurunthotti Kashayam in saganavatham patients before and after treatment
- To have clinical trial drugs "Kurunthotti Kashayam" (int)and "Azhinjil thailam" (ext) in the treatment of "saganavatham"
- To demonstrate the methodology of ancient medical art varmam therapy in treating Saganavatham
- To create a knowledge about the siddha medicine and prove the efficacy of siddha drug for the disease of Saganavatham (Cervical spondylosis)

DISEASE REVIEW- SIDDHA ASPECT

Siddha Medical System is based on the principles of *Iymboothams.* This primordial five elements earth, water, fire, air & ether is indispensable for the evolution of both microcosm (Human) and Macrocosm (Universe). The permutation and combination of these elements *(Panjabootha Panjeekaranam)* form ninety six *Thathuvam.* These ninety six *thathuvams* are the fundamental principle of *Siddha* physiology. These elements are represented in humans by three humours or energies namely *vatha, pitha and silaethumam*.

The Siddhas used the following four methods for obtaining perfect knowledge with respect to health and disease. They are

1. Scriptural testimony
2. Perception or direct observation
3. Inference
4. Reasoning or experimental confirmation

These methods have been applied by them which resulted in providing

1. Appropriate description of 4448 diseases.

2. Botanical and pharmacological knowledge of more than two thousand drugs of vegetable and animal origin.

3. Method of preparation and action of more than 15,000 compound formulations from printed texts.

4. Detailed description of the method of purification and oxidation 0f 150 drugs of mineral and metallic origins for internal use.

5. Description of Varmalogy ideas in the form of Tamil prose and poetry under 120 different titles.

6. Unique diagnostic tools named envagai thervugal, which involves the study of person as a whole as well as his disease.

7. Preventive and promotive aspects of health care in different seasons and at different places

CLASSIFICATION OF VATHA DISEASE:

Siddhas classified the disease of the human body into 4448. The classical *Siddha* literatures like *Pararasa sekaram, Agathiar Ayul Vetham 1200 and Agathiar rathina surukka naadi* describe clearly about 4448 diseases. Vaatha diseases are the major classification among them. *Yugi vathiya Chinthamani, Bogar Vaithyam 700, Agathiar 2000* lists out 80 types of *Vaatha* diseases whereas *Vathanoi Nithanam, Agathiar rathina surukkam* explains 84 types of *Vaatha* diseases. *Theraiyar Vagadam* enlists 81 kinds of *vaatha* diseases.

"தங்குபுவியெங்கும் புகழ்கும் பமுனிசொல்படி தரணியுறு மனுவோருடன்
தங்குபிணி நாலாயிரத்தில் கடியமணியான வாதம் என்பத்தி நான்கும்"

AETIOLOGY OF VATHA DISEASE:

- *Yugi vathiya Chinthamani* 800 enumerates that diet and lifestyle plays an important role in the aetiology of *vaatha* diseases.
  - Intake of food with bitter and astringent taste
  - Intake of curd along with fruits, vegetables and root tubers
  - Daytime sleeping
  - Awakening at night time
  - Starvation
  - Lifting heavy weight above the threshold level
  - Excessive lust.

- *Pararasa sekaram* insists that
  - Excessive intake of food
  - Starvation
  - Constipation
  - Psychological reasons leads to *vaatha* disease.

❖ *Agathiar Gunavagadam* says that *vaatha* disease occur with intake of impure Mercury and lead medications

❖ *Vatha noi nithanam* describes that

"வாதபிணி தேகமதுமோதும் விதமானது வருந்திகேள் இத்தரணியில் வளமாய் கசப்புபுளி துவர்ப்பதிகம் உண்ணலால் மதுகள் குடிப்பதாலும் பொருந்தும் இரவதுதன்னிலே உறக்கம் ஒழிவதால் பட்டினயிருப்பதாலும் மாதுகளோடு அதிகமாய் விரும்பலால் மலஜலம் அடக்குவதினால்"

- Intake of sour and astringent taste foods
- Alcoholism
- Awakening at night time
- Starvation
- Increased sexual indulgence
- Constipation & Urinary retention
- Injuries or energy loss to *varmam* points
- Disturbs the physiological *valinilai* and create the pathological condition called *vaatham*.

PATHOGENSIS OF VATHA DISEASE:

Alteration in lifestyle, dietary habits, mental status,

physical injury or trauma

↓

Imbalance in *Vali nilai(uyir thathu)*

↓

Imbalance in *Varmam* energy flow

↓

Derangement of *Vatham*

↓

Derangement of *udal thathukal*

↓

Disease

CLINICAL FEATURES OF VATHA DISEASE:

According to *Vathanoi nithanam*[22b]

- General Weakness
- Tenderness over hips, thighs, head, both upper limb and lower limb
- Heaviness of body
- Difficulty in walking
- Excruciating pain in the affected bony part

According to *Theraiyar Vagadam*

- Loss of appetite
- Cough
- Insomnia
- Tremors
- Joint Pain
- Constipation
- Yawning
- Head aches
- Excessive salivation

According to *Agathiar Naadi & Agathiar 2000*

- Weakness of both upper & lower limbs
- Increased rigidity of the body
- Gastric pain
- Loss of appetite
- Oliguria / Azoospermia
- Diarrhoea

SAGANA VATHAM:

Saganavatham is one among 80 types of *vaatha* diseases. The clinical features of Saganavatham are explained in *Yugivaithya Chinthamani* and *Parasara Sekaram* as follows:

"கேளுமே கழுத்தின்கீ ழரைக்கு மேலுங்
கெடியான கரமிரண்டு மிகவே நொந்து
வாளுமே சரீரமெல்லாம் கனத்திருக்கும்
வலிபர்க்கு மனங்கண்ணு மயக்கமாகும்

ஏளுமே யிரண்டுகண்ணு மெரிச்சலுண்டா
மேற்றமாய் சலந்தானு மிறுகிக்காணுந்
தேளுமே கொட்டினது போற்கடுக்கும்
சகனவாதத்தினிட தீர்க்கந்தானே"

"கண்டதோர் சிகன்ன வாதங் கழுத்தின் கீழரைக்கு மேலும்
மண்டலங் கரமிரண்டு மிக நொந்து கனத்திருக்கும்
மண்டியே திமிர்த்துக் குத்தும் வலி மிகத்துளைவுண்டாம்
வண்டமர் குழலினாளே மதியினாலுள்ளுவாயே"

- Pain Extending from neck to hip and both upper limbs; A sort of heavy feel in the body.
- Burning sensation in the eyes. Presenting of Urinary symptoms like concentrated urine probably because of bladder disturbances.
- Mental symptoms and reducing eye sight in the Young adults.
- Sharp and Stinging (lancinating) pain with agony

DIFFERENTIAL DIAGONSIS OF VATHA DISEASE:

PIDARI VATHAM:

Vatha nithanam 250 and Vathanoi thogudhi states that *Pidari vaatham* is characterized by

"பிடரினிடைதுஞ்சு கொடி மடமயிலே கேளினிபிடரியில் வாதமதுதான்
பின்னியே நரம்புகள் உன்னிவலிவாகியே பெரும்திமிராகி உளையும்
இடமுற்நாளமது மேலே புடைத்தெழும் இனியகழுத்தடி கனத்து வீங்கும்
இந்தயிடமுளையுமே குனியஒட்டாது காண் ஏற்றவிறை கிடுகிடுக்கும்
விடமுறு புயமதில் குத்திவலியாகவே எங்கும் உளைந்து நோகும்
விறும்நரம்பிடமானது வலிக்குமே விறையது தலையிலுண்டாகும்
திடமொடு பொருத்துகளிடமது உளையுமே தீ அனல்போல் கந்தும்
தீட்சையுறும் முருகர் சொல்படியே கும்பமுனி திண்ணமுடனுரைத்தார்"

The above lines from *Vatha Noi Thoguthi,* Verse 59 state that *Pidari vatham* is characterized by

- Radiating pain along the neck
- Swelling around the neck region
- Restricted flexion of the neck
- Tremors
- Pain around the shoulders
- Sense of numbness over the head and
- Multiple joint pain with burning sensation

KUMBA VATHAM:

"நவிலவே தோள்மீதம் கரத்தின் நசவுண்டாகும்
நலிந்து மெத்த வாகிய நசவுண்டாகும்
கவிலவே கன்னமொடு நயனங் தானுங்
கடுத்துமே விறுவிறுப்பு மெரிவுங் காணும்

துவிலவே துடிப்பாகும் சிரசு தன்னிற்
சுழற்றியே நாபிக்கீழ் வலியுமுண்டாம்
அவிலவே வருகும்ப வாதந் தானே"

- ❖ Tenderness over the shoulders & both upper limbs
- ❖ Pain in the cheeks around the orbits
- ❖ Head ache
- ❖ Hypogastric pain
- ❖ Glossitis

ENVAGAI THERVUGAL:

It refers to eight diagnostic tools used in Siddha Medical System. This involves

- ❖ Examination of the tongue *(NAA)*
- ❖ Examination of colour *(NIRAM)*
- ❖ Examination of the speech *(MOZHI)*
- ❖ Examination of eyes *(VIZHI)*
- ❖ Examination of skin-tactile functions (SPARISAM)
- ❖ Examination of the faeces *(MALAM)*
- ❖ Examination of the Urine *(MOOTHIRAM)*
- ❖ Examination of the Pulse *(NAADI)*

Among them, *naadi* (Pulse diagnosis) and *neikkur*i (a kind of urine examination) are very unique to Siddha Medicine. These eight tools are said to be weapons of a physician.

NAA (Tongue):

Tongue has been regarded as an invaluable clinical indicator of health and disease. This includes examination of tongue for colour, salivation, ulceration, fur-formation, fissure, eruptions, status of teeth and gum, speech, movement and pulse.

NIRAM (Colour):

Colour of the body, face, eyes, teeth and tongue are noted.

MOZHI (Speech)

Voice coherency, modulation of tone and pitch control in normal, conscious, delirious and comatose states.

VIZHI (Eyes):

The eyes are considered as the windows of the body. It is an indispensable parameter for the physician in the diagnosis of a disease. The colour of eyes varies according to the humoural constitution of the body. Eyes are noted for the following features colour, ulceration, pallor, congestion, lacrimation, oedema, infection of cornea, condition of pupil and vision.

SPARISM (Tactile Perception):

Touch, pain, sweat and temperature were examined. Hot or cold or mixed perspiration, numbness, chillness, oily or dry cracking skin, thickening of hair or falling of hair, hair raising like thorn, chillness of nose, eyes, ears, condition of fontenelle, umbilicus, soles, palm, thickening or pigmentation of skin, rashes or inflammatory changes of skin, obesity or emaciation of body were noted.

MALAM (Stools):

Nature, colour, quantity, consistency, odour, froth were examined.

MOOTHIRAM (Urine examination):

This includes two steps.

i) *Neerkuri* (Physical appearance of urine):

It is an indicator of many diseases. Urine is noted for colour, consistency, smell, forth and residue, etc.

ii) *Theran's Neikkuri* (Oil Drop Urine Examination):

The three humours prevalence was evaluated by this method. A unique diagnostic method called *Neikkuri* is advocated with the use of sesame oil in freshly collected urine in early morning.

VATHA NEER – A drop of oil instilled on the urine, spreads like a shape of a snake.

PITTHA NEER – A drop of oil instilled on the urine, spreads like a shape of a finger ring.

KABA NEER – A drop of oil instilled on the urine, spreads like a shape of a Pearl.

As a prognostic tool:

It is used for diagnosis of a disease and also for prognostic assessment.

NAADI (Pulse diagnosis):

The science of pulse reading is peculiar to Siddha system of medicine. *Naadi,* in Siddha Medicine is an applied science and the basis for the diagnosis of diseases. By feeling the pulse with the fingers, the physician first assumes the physiological and pathological state of the person examined, before deciding the line of treatment. According to Siddhars, pulse is the manifestation of *Sakthi nilayam* (vital force) in a living being.

Science defines **pulse** as 'beat of an artery', felt at the wrist, with the fingertip. The science of pulse is based on three life factors viz. *Vatham, Pitham and Silaethumam.* The normal ratio is 1: 1/2: 1/4 respectively.

“வலங்கிய வாதம் மாத்திரை யொன்றாகில்
தழங்கிய பித்தந் தன்னிலரை வாசி
அழங்குங் கபந்தா னடங்கியே கல்லாடில்
பிறைங்கிய சீவாக்குப் பிசகொன்று மில்லயே”

Traditionally, this science of pulse reading is being taught by Guru to his disciples. Diagnosis of the disease by means of the pulse requires great skill and experience.

Apart from this, there are *Guru naadi, bootha naadi* etc which can be learnt only from *aasans* or gurus which can be understood only when acquainted with immense knowledge. The three kinds of humours are ascertained from three kinds of movements of the pulse i.e swift, medium and slow. The textual evidence of Siddhars immensely helps in tracking down the diagnosis and prognosis of disease by the nature of pulse reading.

Varma thathuva nool reveals that *‘Naadi’* does not refer to something that can be measured such as the rate of flow of blood. It is rather the energy or satthi that travels through its own specified pathway in the body. *Naadi* may also refer to physical structures like blood vessels and nerves. It is therefore a term whose measuring should be referred from the context of usage. To establish the flow of *vatham, pitham and silaethuma naadi,* it is essential to know the flow of *idakalai, pingkalai and suzhumunai naadi* respectively to ascertain the diagnosis of a disease. These *naadis* depict the flow of *vayus abanan, pranan and samanan.*

DISEASE REVIEW - CERVICAL SPONDYLOSIS

DEFINITION

Cervical spondylosis is defined as arthorosis of the posterior intervertebral joints in the cervical vertebrae. It is common in the middle aged and in the elderly, particularly in those whose occupation involves a posture of prolonged neck flexion.

AETIOLOGY

- Ageing is the major factor for developing cervical osteoarthritis (cervical spondylosis). In most people especially in females after the menopausal age of 50, the discs between the vertebrae become less spongy and provide less of a cushion. Bones and ligaments get thicker, encroaching on the space of the spinal canal.
- Occupation People in certain occupations who perform specific activities – overweight lifting and not exercising or prolonged bending and twisting, such as gymnasts or other athletes may put more stress on their necks.
- Mechanical load applied to the spine.
- Mechanical instability – Altered posture might also play a role in the development of spinal changes that result in cervical spondylosis and Stress.

EPIDEMIOLOGY

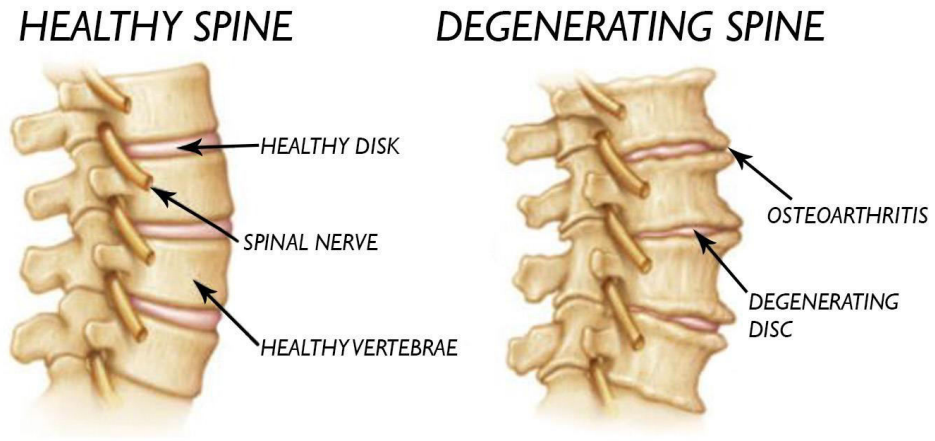
SEX:

The prevalence of cervical spondylosis is similar for both sexes, although the degree of severity is greater for males. Spondylotic changes in the cervical spine occur at solitary disc space levels in 15-40% of patients and at multiple levels in 60-85%. The discs between the third and seventh cervical vertebrae are most commonly affected.

AGE:

It occurs as early as 25 years of age. As age increases so does the incidence rate. 60% of the population older than 45 years of age and 8% older than 65 years of age account for the case of cervical spondylosis reported. In males, the prevalence was 13% in the third decade, increasing to nearly 100% by age 70 years. In females, the prevalence ranged from 5% in the fourth decade to 96% in women older than 70 years.

PATHOGENESIS:



- Degenerative changes develop in the vertebral column with advancing age. The nucleus pulposus of the intervertebral discs undergo degeneration with reduction in their fluid content, and this results in their collapse and narrowing of the intervertebral spaces.
- The annulus fibrosis also shows degenerative changes and they protrude backwards behind the vertebral bodies to form ridges. Osteophytes develop from the vertebral bodies and laminae resulting in compression of the nerve roots in the intervertebral foramina.
- The cord may be compressed by osteophyte bars formed in the midline behind the vertebral bodies or the roots may be compressed by osteophytes growing into the intervertebral foramina.

- Degenerative changes are seen most markedly and symptoms are more frequent in the cervical and lumbar regions of the vertebral column. In addition to the higher mobility of the spine in these regions which accounts for greater predilection to degenerative changes, it is also likely that subjects who develop cervical spondylosis have relatively narrower spinal canals.
- In addition to the bony changes, soft tissue changes develop. The ligament flava lose their elasticity and tend to buckle forwards when the cervical spine is extended. This leads to compression of the posterior aspect of the cord.
- In the inter-vertebral foramina fibrosis of the dural sheaths contributes to further pressure on the spinal nerves and their roots.
- Pressure on the spinal arteries and the vertebral arteries during their course in the bony structures leads to secondary vascular changes which cause their occlusion and ischemic damage to the cord and lower brainstem.
- The clinical presentation may vary widely from that of a myelopathy, radiculopathy or both. The site of lesion may be at the actual level of compression, or even distant from that, on account of vascular occlusion.
- In the early stage it is localised to two or three cervical vertebral segments, due to degeneration of the intervertebral disc with narrowing and osteophyte formation at the anterior and posterior margins. The osteophytes cause narrowing of the intervertebral foramen resulting in nerve root irritation.
- In the later stage there is a generalised degenerative arthrosis of the posterior intervertebral joints of the whole cervical spine. In the extreme form there is compression of the spinal cord with myelopathy and symptoms of cord lesion.

PREDISPOSING FACTORS

1. Previous injuries/trauma to the cervical spine
2. Ageing factors
3. Repetitive Strain injury (RSI) due to lifestyle without ergonomic care
4 .Occupation related factors
5. HLA related genotype aberration
6. Smoking

7. Diabetes

8. Hypertension

9 .Mental health illness-Depression/anxiety

CLINICAL FEATURES:

SYMPTOMS

- Pain in nape of the neck (local/reffered pain)
- Radiating pain in upper limbs
- Tenderness, Numbness
- Stiffness of neck
- Restriction of movements of neck
- Giddiness
- Sensory loss & paresthesiae in the corresponding dermatomes(due to sensory root involvement)
- Weakness of muscles supplied (due to motor root involvement)

SIGNS:

Spurling's sign

Cervical extension results in narrowing of the vertebral canal producing severe pain in the neck and shoulder

DIFFERENTIAL DIAGNOSIS :

1. Compression of cord or root (TB, Secondaries or neurofibromas)
2. Peripheral nerve lesions(distal ulnar or median nerve)
3. Motor neuron disease
4. Syringomyelia
5. Multiple sclerosis

COMPLICATIONS

CERVICAL MYELOPATHY

Definition

If cervical spondylosis results in pressure on the spinal cord (cervical stenosis), it can cause spinal cord impairment, a condition called cervical myelopathy.

Causes

1. Compromise of the spinal cord
    - Cervical spondylosis.
    - Acute disc herniation.
    - Inflammatory arthritis
    - Spinal stenosis.
    - Trauma
2. Congenital and developmental defects
    - Syringomyelia
    - Neural tube formation defects
3. Spinal neoplasms
4. Physical agents
    - Decompression sickness
    - Injury
    - Radiation
5. Toxins
    - Nitrous oxide
6. Metabolic and nutritional disorders
7. Multiple sclerosis

Patho Physiology

1. Direct pressure on the spinal cord.
    a) Mechanical Factors
        i) Static
        ii) Dynamic.

2. Ischemia of the cord

i) Compression and obstruction of small vessels within the cord.

ii) Compression of the feeding radicular arteries within the intervertebral foramen.

3. The morphological changes within the cord include:

i) Degeneration and loss of nerve cells

ii) Cavitations and proliferation of glia within the grey matter.

iii) Demyelization of the lateral and posterior columns.

iv) Proliferation of small blood vessels with thickening of the vessel walls

Clinical Features

Symptoms of cervical spondylosis with myelopathy include:

- Tingling, numbness, and/or weakness in the arms, hands, legs
- Lack of coordination and difficulty walking
- Abnormal reflexes
- Muscle spasms
- Loss of control over bladder and bowel
- Gait abnormalities

Clinical syndromes of Spondylotic Myelopathy

- Posterior cord syndrome.
- Anterior cord syndrome
- Central cord syndrome
- Brown-sequard syndrome

CERVICAL RADICULOPATHY

Cervical Radiculopathy is the clinical description of pain and neurological symptoms resulting from any cause that irritates a nerve in the cervical spine. When any nerve root in the cervical spine is irritated through compression or inflammation, the symptoms can radiate along that nerve's pathway into the arm and hand.

Causes of Cervical Radiculopathy

Any condition that injures or somehow irritates the cervical nerve can cause cervical radiculopathy. The most common causes include:

Cervical Herniated Disc.

If the inner material of the cervical disc herniates or leaks out and inflames and/or impinges on the adjacent nerve, it can cause a cervical radiculopathy.

Cervical Spinal Stenosis.

As part of the degenerative process of the cervical spine, changes in the spinal joints can lead to tightening of the space for the spinal canal.

Cervical Degenerative Disc Disease.

When the cervical spine degenerates over time, it can result in degenerated discs and a pinched nerve

Infrequently, cervical radiculopathy can be caused by other conditions, such as a tumor, fracture or sarcoidosis, which can compress or cause damage to the cervical nerve roots.

Clinical Features:

The most common complaint is neck pain, which limits motion and is aggravated by neck extension. Pain also may radiate into one arm, in a pattern characteristic of particular root involved. The type of pain also can vary. Some patients describe dull, all over pain; others describe the pain as severe burning or sharp. Patients may feel tingling, "pins and needles" or numbness.

Certain neck movements like extension, side to side rotating it may increase the pain. Some patients report that pain decreases when they place a hand behind their head; the movement may be relieving the pressure and traction on the nerve root which then lessens their symptoms.

Table 1. The most common clinical manifestation of cervical disc herniation

MANIFESTATION	C4C5	C5C6	C6C7	C7T1
ROOT COMPRESSED	C4	C5	C6	C7
MOTOR WEAKNESS	Deltoid	Biceps, supra and infraspinatus.	Brachiradialis	Triceps, fingers and wrist extensors
SENSORY LOSS	Lateral shoulder	Lateral arm and forearm,thumb andlateral aspect of index finger	Middle finger	Ring and little finger
DIMINISHED REFLEX ACTIVITY	Deltoid	Biceps	Triceps	Finger flexion

The above table shows usual cervical root syndromes (radiculopathy). C6-C7 disc is most frequently herniated about 2/3 of cervical disc herniation. C5-C6 disc is involved about 20%, C7-T1 about 10% and C4-C5 about 2%.

RADICULO MYELOPATHY

Combination of radiculopathy & myelopathy symptoms are found.

Signs and Symptoms:-

I. At $C_3 – C_4$ Level

Pain in the neck and occipital area, paraesthesia and weakness of upper limbs early. Paralysis of 9^{th}, 10^{th} and 11^{th} cranial nerves, lower part of trapezius, supra spinaturs, infra spinatus and diaphragm may occur. Exaggerated deep tendon reflexes, absence of abdominal & cremastic reflexes, extensor plantar on both sides, sphincters affection.

II. At the level of C_5

Quadriplegia, paralysis of biceps, deltoid, rhomboideus, brachialis and supinator muscles. Diminished biceps (C_5-C_6) and supinator (C_5-C_6) jerks, Exaggerated triceps jerks and inversion of the radial reflex may occur.

III. At the level of $C_5 – T_{12}$

Signs of lower motor neuron lesion, segmental sensony loss in upper limbs and signs of upper motor neuron lesion in the lower limbs may occur.

IV. At the level of C_8-T_1

Spastic paralysis of trunk and lower limbs, paralysis of flexor of wrist, fingers and small muscles of hand and exaggeration of lower limbs tendon reflexes.

Autonomic Symptoms:-

Various autonomic symptoms can be produced by cervical disc disease (e.g) vertigo, flushing, tinnitus and visual blurring. These are mediated by the sympathetic contribution to the sinu verterbal nerves. It also result in fall of BP, sweating and increased intestinal motility.

INVESTIGATIONS

- **X-Ray Neck**

VIEWS	FEATURES
➢ Anterior posterior	1. Loss of normal cervical lordosis
➢ Lateral	2. Spondylotic bars
➢ Oblique	3. IV disc narrowing and subluxation

- **Myelography**

  It provides evidence of

  - Nature of cord
  - Nerve roots
  - Dimensions of the vertebral canal and
  - Root outlets

- **CT Scan and MRI**
  - The extremely valuable after myelography
  - It provides evidence of
    i. Overall axial dimensions of the canal & the foramina
    ii. Better assessment of cord compression

- MRI is the first choice of investigating suspected lesions of spinal cord

- **EMG Study**
  - It provides differentiation of root lesions from other plexopathies and thoracic outlet problems

MANAGEMENT:

The most optimal treatment has not yet been established.

Treatment is usually conservative in nature. Non-surgical treatment is usually the most appropriate course of initial management

1. The current clinical treatments mainly include administration of non-steroidal anti-inflammatory drugs, muscle relaxants, physiotherapy, analgesics, and so on

2. Physical modalities or postural advice in daily activities, work, and hobbies

3. Lifestyle modifications.

4. Stress management

5. There have been several trials and systematic reviews into the use of a structured physical therapy programme for the treatment of cervical spondylosis and its sequelae. Recent reviews reach similar conclusions.

6. Surgery is occasionally performed. Many of the treatment modalities for cervical spondylosis have not been subjected to rigorous, controlled trials. Surgery is advocated for cervical radiculopathy in patients who have intractable pain, progressive symptoms, or weakness that fails to improve with conservative therapy. Surgical indications for cervical spondylotic myelopathy remain somewhat controversial, but most clinicians recommend operative therapy over conservative therapy for moderate-to-severe myelopathy.

TREATMENT

The treatment includes

1. Physiotherapy with short wave diathermy to the neck,
2. Graded cervical traction may help to relieve pressure on the nerve roots
3. Analgesics.
4. When the pain is controlled the patient is taught shoulder bracing and neck exercises.
5. In the acute painful stage, a cervical collar is prescribed.
6. If definite bony ridges are demonstrable in cases with cord compression surgery to relieve pressure is indicated.

DRUG REVIEW

The comprehensive knowledge of the drug is very important to the physician because without knowledge of the drug, the patient cannot be treated properly. In this way, all *siddha* classics advocate specific medicine for particular disease in single & compound formulation. Hence sufficient attention should be given while selecting a drug.

The drug taken for the present study is *Kurunthotti Kashayam(KK)* from the Siddha literature *Vatha Noi Nithanam-800.* Following is the review about the drugs used in this formulation.

The literature poem of the drug Kurunthotti Kashayam is given below,

குறுந்தொட்டி கஷாயம்

“உறவாகவே குறுந்தோட்டியின் குடிநீரு உலகறிய ஓதுவது கேளு

உறு சிறுமுட்டிவேர் வெள்ளாமணக்குவேர் உரைத்த கருநொச்சி வேரும்

திறமாய் சகசரமதின் வேரு வெள்ளுள்ளி திடமுடன் தேவதாரம்

திட்டமிட்டமுடனே இரண்டரத்தை வகையே சமன் திருந்து கழஞ்சொன்றரை

குறையாது இரண்டுபடி அப்புதனிலே இடுகுறுக்கியது எட்டிலொன்றாய்

கூறும் இந்துப்பு வறுபொடி செய்து வெருகடி குடித்து மேலிட்டிரு நேரவும்

அறையாமலே குடிஈராறு நேரவும் அந்தியொடு சந்தியதிலே

அதலுமே வரதமது உடலுவிட்டு நீங்குமே அருளு மிதுமுனி யோதினார்

- வாதநோய் தொகுதி, ப.எண் 192

INGREDIENTS OF KURUNTHOTTI KASHAYAM

- Sitramutti ver
- Amanakkuver
- Nochi ver
- Sagasaram ver
- vellulli
- Devatharu
- Sitrarathai

PREPARATION:

All herbal drugs are dried and purified as per classical text procedure and then grinded into kashayam powder.

DOSAGE **: 5**gm b.d with addition of indhupu (1gm) with Kashayam (30-60ml) two times a day, After food

DURATION **:** 21 days

INDICATIONS **:** Vaadham theerum**.**

AZHINJIL THAILAM

INGREDIENTS OF AZHINJIL THAILM:

- Azhinjil vithai
- Pungam viththu
- Kadukkai vithai
- Thantrivithai
- Karpokarisi
- Etti vithai
- Nallennai
- Vaeppennai

PREPARATION:

All the ingredients are coarsely powdered and grinded with Neem oil, then mixed with gingely oil and heat it till it attains kadugu patham. The nthe oil is filtered and stored in an air tight container.

INDICATION:

- Cervical pain
- Swelling

SITTRAMUTTI

Botanical name: Sida cordifolia

Family : Malvaceae

Suvai : Thuvarpu

Thanmai : Thatpam

Pirivu : Inippu

Part used : Samoolam

Chemical constituents:

- Ephedrine
- Pseudoephidrine
- Sterculic acid
- Malvic acid
- Coronaric acid
- Saponin
- Hypaphorine
- Ecdysterone
- Indole alkaloids

Actions:

- Emollient

Gunam:

"அத்தி சுரமுதல் அனந்தசுரம் பித்தமும் போம்
மெத்த விழிகொளியாம் வீறுதயி-லத்திற்காம்
நற்றா மரைத்திருவு நாடு மெழிற்றிருவே!
சிற்றாமுட் டித்துரைச் செப்பு"

- குணபாடம் மூலிகை வகுப்பு ப.எண் 446

AAMANAKKU

Botanical name: Ricinus communis

Family : Euphorbiaceae

Suvai : kaippu

Thanmai : Veppam

Pirivu : Kaarppu

Part used : Leaves, root and seed

Chemical constituents:

- Ricinine
- N-Dimethylricinine
- Asesquiterpenoid
- Ricinoleic acid
- Isoricinoleic acid
- Dyhydroxy stearic acid

Actions:

- Anti-vatha
- Immunomodulatory
- Hepatoprotective activity
- Anticancer activity

Gunam

“வாதத் தொடக்கை வரவொட்டாமற் படிக்கும்

காதத்து க்ப்பாற் கடியுமே சூதத்தைப்

பேரண்டப் பந்திக்கும் பேதிக்கு நோய்க்காட்டை

யேரண்ட மென்பதினியே”

- குணபாடம் மூலிகை வகுப்பு ப.எண் 38

KARUNOCHI VER

Botanical name: Vitex neguno

Family : Verbenaceae

Suvai : Kaippu

Thanmai : Veppam

Pirivu : Kaarppu

Part used : Root

Chemical Contituents:

- Vitexoside
- Negundin A
- Negundin B
- Agnuside
- Vitrofolal E
- α - pinene
- β- pinene
- Caryophyllene epoxide
- α-selinene

Actions:

- Analgesic
- Anti inflammatory
- Anti arthritic
- Antipyretic

Gunam:

"நோயா கலியை நொடிக்கு ளருந்தவெம்மை

யோயா மணாளு முயர்த்துதலுக்-காய

வந்தமுதல் நண்பாகி வாதத்தை யேயுறவாற்

சிந்துவா ரங்கனலுந் தீ"

- தேரன் வெண்பா
- குணபாடம் மூலிகை வகுப்பு
  ப.எண் 628

SAGASARAM

Botanical name	**:**	*Ecbolium linnaenum*
Family	:	Acanthaceae
Common	:	Blue fox Tail
		Blue Justicia
Tamil names	:	Kurinji
		Pachai kanakambaram

Medicinal uses:

- It is a synonym of *Ecbolium lingustrinum*
- The roots of this plant are used in Jaundice and Menorrhagia.
- The plant is used for Gout and dysuria
- Decoction of leaves for stricture
- Roots aare given in jaundice, menorrhagia and Rheumatism.

VELLULLI

Botanical name: *Allium sativum*

Family : Liliaceae

Suvai : Kaarppu

Thanmai : Veppam

Pirivu : Kaarppu

Part used : Rhizome

Chemical Contituents:

- Glutmylcysteine
- Steroidal glycosides
- Fructan
- Pectin
- Adenosine
- Nicotinic acid

Actions:

- Antioxidant activity
- Carminative
- Expectorant
- Diuretic
- Tonic

Gunam:

"சன்னியொடு வாதந் தலைநோவு தாள்வலி

மன்னிவரு நீர்க்கோவை வன்சீதம்- அன்னமே!

உள்ளுள்ளி கண்பாய் உளைமூல ரோகமும் போம்

வெள்ளுள்ளி தன்னால் வெருண்டு"

- குணபாடம் மூலிகை வகுப்பு ப.எண் 846

DEVADHARU

Botanical name: *Cedrus deodra*

Family : Pinaceae

Suvai : Siru Kaippu

Thanmai : Veppam

Pirivu : Kaarppu

Part used : Wood

Chemical Constituents:

- α- himachalene
- β-himachalene
- Himachalol
- Allohimachalol
- Himadarol
- Isocentdarol
- Centdarol

Actions:

- Astringent
- Febrifuge
- Anti inflammatory activity[]
- Anti arthritic activity[]
- Antidiabetic activity[]

Gunam:

"தேவதா ரக்குணந்தான் சேர்த்துவளர் பீனிசத்தைக்
காவகத்தி லோட்டுங் கரப்பலவே - மாவலவர்
சொல்லும்பு ராண சுரமொடுநீ ரேற்றத்தை
வெல்லு மனற்றணிக்கு மெய்"

- குணபாடம் மூலிகை வகுப்பு ப.எண் 547

SITTRARATHTHAI

Botanical name: *Alpinia galanga*

Family : Zingiberaceae

Suvai : Kaarppu

Thanmai : Veppam

Pirivu : Kaarppu

Part used : Root

Chemical Constituents:

- Caemperol
- Caempferide
- Galangin
- Alpinin

Actions:

- Anti infalammatory
- Analgesic
- Anti allergic
- Anti viral
- Anti oxidant

Gunam

"வாதபித் தங்கரப்பான் வாதஞ் சிரோரோகஞ்

சேர்ந்தகப முத்தோடஞ் சீதமொடு - நேர்ந்தசுரம்

மற்றரத்தைக் காட்டி வருமிரும லுந்தீரும்

சிற்றரத்தை வன்மருந்தால் தேர்."

- குணபாடம் மூலிகை வகுப்பு ப.எண் 36

PERARATHTHAI

Botanical name: *Alpinia officinarum*

Family : Zingiberaceae

Suvai : Kaarppu

Thanmai : Veppam

Pirivu : Kaarppu

Part used : Root

Chemical Constituents:

- Galangin
- Quercetin
- Emodin
- Flavonoids
- Sitosterols
- Gamma-Sitosterol

Actions:

- Anti inflammatory
- Anti hyperlipedemic
- Osteoblast activity
- Anticancer

Gunam:

"அரத்தை கபத்தை அறுக்குங்கால் ஓட்டுஞ்
சிரத்திலுறும் ஈளையைச் சிதைக்கும் - இரைத்துவரும்
பித்ததோ டத்தைப் பிறவலிப்பை மற்றிவிடும்
உற்றசர்வ வல்லிடம்போக் கும்."

- குணபாடம் மூலிகை வகுப்பு ப.எண் 37

INGREDIENTS OF AZHINJIL THAILAM

AZHINJIL VITHAI

Botanical name: *Alangium salvifolium*

Family : Alangiaceae

Suvai : Kaippu

Thanmai : Veppam

Pirivu : Kaarppu

Part used : Seeds

Chemical Constituents:

- Salviifoside A
- Salviifoside B
- Salviifoside C
- Salicin
- Kaempferol
- Kaempferol 3-O-b-D-glucopyranoside

Actions:

- Anti inflammatory
- Anlgesic
- Diuretic
- Anthelmintic
- Anti arthritic

Gunam:

"அங்கோல வித்தை யயின்றான்முன் போலவினை
யங்கோல வித்தை யடங்குமே எ யங்கோல
முண்டா மரைவாசி யுட்பலமே லாகியதை
யுண்டா மரைவாசி யுள்."

- குணபாடம் மூலிகை வகுப்பு ப.எண் 52

PUNGAN VITHAI

Botanical name: *Pungamia piannata*

Family : Fabaceae

Suvai : Kaippu, Thuvarpu

Thanmai : Veppam

Pirivu : Kaarppu

Part used : Seeds

Chemical Constituents:

- Karangin
- Pongamol
- Pongagalabrone
- Pongapin
- Pinnatin
- Kanjone

Actions:

- Anti inflammatory
- Anti ulcer activity
- Astringent
- Alterative
- Parasiticide

Gunam:

"புங்கின்விதை காற்கிரந்தி புண்கரப்பான் காதெழுச்சி
அங்கசன்னி கண்ணோய்க்கும் ஆம்பேதி - யுங்கட்டும்
காட்டுப்புங் கின் விதைக்கு கண்டதே மற்சொறிமேய்ப்
பூட்டுப்பங் கின்வாய்வும் போம்."

- குணபாடம் மூலிகை வகுப்பு ப.எண் 691

KADUKKAI

Botanical name: *Terminalia chebula*

Family : Combretaceae

Suvai : Thuvarppu

Thanmai : Veppam

Pirivu : Inippu

Part used : Seeds

Chemical Constituents:

- Chebulanin
- Ellagic acid
- Corilagin
- Chebulinic acid
- Chebulagic acid
- Terminolic acid
- Chebuloside II

Actions:

- Anti microbial
- Astringent
- Cardio protective
- Antidiabetic activity

Gunam:

"தாடை கழுத்தக்கி தாலு குறியிவிடப்
பீடை சிலிபதமுற் பேதிமுடம் - ஆடையெட்டாத்
தூலமிடி புண்வாத சோணிகா மாலையிரண்
டாலமிடி போம்வரிக்கா யால்."

- குணபாடம் மூலிகை வகுப்பு ப.எண் 207

THAANDRIKKAI

Botanical name: *Terminalia bellerica*

Family : Combretaceae

Suvai : Thuvarppu

Thanmai : Veppam

Pirivu : Inippu

Part used : Seeds

Chemical Constituents:

- Alkaloids
- Coumarin
- Flavone
- Glycosides
- Bellericoside
- Bellericanin
- Chebulaginic acid
- Chebulagic acid

Actions:

- Analgesic
- Anti inflammatory
- Astringent
- Expectorant
- Laxative
- Tonic

Gunam:

"சிலந்திவிடம் காமியப்புண் சீழான மேகங்

கலந்துவரும் வாதபித்தங் காலோ - டலர்ந்துடலில்

ஊன்றிக்காய் வெப்ப முதிரபித் துங்கரக்குந்

தான்றிக்காய் கையிலெடுத்தால்"

- குணபாடம் மூலிகை வகுப்பு ப.எண் 513

KARBOGARISI

Botanical name: *Psoralea corilifolia*

Family : Fabaceae

Suvai : Kaippu

Thanmai : Veppam

Pirivu : Kaarppu

Part used : Seeds

Chemical Constituents:

- Alkaloids
- Tannins
- Saponins
- Sterols
- Phenol
- Proteins
- Flavanoids

Actions:

- Analgesic
- Anti fungal
- Antibacterial
- Laxative
- Stimulant

Gunam:

“கார்போக மாமரிசி கண்டாற் கரப்பாண்புண்

பீர்சகுவ நஞ்சிவைபோம் பித்தமுண்டாம் - பார்மீதில்

வாதகப நமைச்சல் வன்சொறி சிரங்குமறுஞ்

சீத மலர்க்குழலாய் செப்பு.”

- குணபாடம் மூலிகை வகுப்பு ப.எண் 311

ETTI VITHAI

Botanical name: *Strychnos nuxvomica*

Family : Loganaceae

Suvai : Seed-Kaippu

Thanmai : Veppam

Pirivu : Kaarppu

Part used : Seeds

Chemical Constituents:

- Strychnine
- Brucine
- Brucine N-oxide
- β-colubrine
- Icajine
- Vomicine
- Novacine

Actions:

- Antiseptic
- Purgative
- Tonic
- Carminative
- Stimulant
- Diuretic

Gunam:

"கைக்கறுப்பு சன்னி கடிவிடங்குட் டீதைவவலி

எய்க்கவரு தாதுநட்டம் என்பதும்போம்-மைக்கண்ணாய்

கட்டி கரப்பாண் கனமயக்கு பித்தமுமில்

எட்டிபரக் கொட்டையினா லே."

- குணபாடம் மூலிகை வகுப்பு ப.எண் 148

NALLENNAI

Botanical name: *Sesamum indicum*

Family : Pedaliaceae

Suvai : Inippu

Thanmai : Thatpam

Pirivu : Inippu

Part used : Seed oil

Chemical constituents:

- Alkaloids
- Flavonoids
- Tannins
- Phenol
- Phytate

Actions:

- Demulcent
- Laxative
- Nutritive
- Emolient

Gunam:

"புத்திநயனக்குளிர்ச்சி பூரிப்பு மெய்ப்புளகஞ்
சத்துவங் கந்தி தனியிளமை-மெத்தவுண்டாங்
கண்ணோய் செவிநோய் கபாலவழல் காசநோய்
புண்ணோய்போ மெண்ணெய்யாற் போற்று."

- குணபாடம் மூலிகை வகுப்பு ப.எண் 164

VEPPENNAI

Botanical name: *Azadirachta indica*

Family : Meliaceae

Suvai : Kaippu

Thanmai : Veppam

Pirivu : Kaarppu

Part used : Seed oil

Chemical constituents:

- Azadirachtin and Nimbin along with triglycerides
- Stigmasterol
- Campesterol
- beta-sitosterol
- This oil also contains fatty acids, namely Omega-6, Omega-9, stearic acid and palmitic acid.

Actions:

- Stimulant
- Antiseptic
- Insecticide
- Anthelmintic
- Anti inflammatory

Gunam:

வாதம்போம் பித்தமிகும் மாறாக்கி ரந்தியொடு

மோதுகரப் பான்சிரங்கு முன்னிசிவும்-ஓதுடலின்

நாப்ப ணுறுசுரமு நாடுசன்னி யுந்தொலையும்

வேப்பநெய் யென்யென்றொருக்கால் விள்ளு.

- குணபாடம் மூலிகை வகுப்பு ப.எண் 858

INGREDIENTS OF KURUNTHOTTI KASHAYAM

Sagasaram Ver

Aamanakku Ver

Dhevadaru

Nochi Ver

Kurunthotti Ver

Sitrarathai

Perarathai

Vellulli

KURUNTHOTTI KASHAYAM

AZHINJIL THAILAM

VARMAM

The points where life forces resides and flows in the human body are known as Varmam.

It has gathered various names like, Vasi, Kaalam, Pranan, Kalai, Suvaasam, Saram, Yogam, Param, Sivam, etc,.This has been mentioned in the tamil text vaakata nithanam.

HISTORY OF VARMAKALAI:

Varmakalai is (the art of varmam) is considered to be very auspicious. It is believed that Lord Shiva taught tis art form. Lord Shiva taught varmam to his son Lord Murugan, later Lord Murugan taught varmam to Agasthiyar, Nanthi devar and their disciples. Varmam art has been sustained and nourished for centuries by the tradition of aasan(the master) and disciple. The master has the responsibilities to share his experimental and knowledge of this art to his trusted students, Now it is well populared in south india.

VARMAM POINTS:

The places where the *Varmam* energy resides and activates both body and life-energy are *Varmam* points. These points are located in the nerves, naadi, muscle and bones. They are the sites of bio-energy which aid physiological functions of the body.

It is also said that *Varmam* points are the places where the vital energy *Vaasi* strikes.

Most of the *Varmam* texts enlist 108 *Varmam* points of which 12 are *padu varmams* and 96 are thodu varmams. *Padu varmams* are the varmam points which are directly connected to brain energy and serve as major energy storage points . According to "*Pingala nigandu"*, the word *'padu'* means brain. *Thodu varmams* are the *varmam* points which are connected to *padu varmams.* The word 'thodu' refers to touch. It means through the act of touch, one varmam point is connected to another varmam point. Such a way, eight *thodu varmams* are connected to one *padu varmam* i.e 8 x12 = 96 *Thodu varmam*. They serve as minor energy storage points.

The total number of Varmam points which accounts to 108 comprises two terminologies Varmam and Kaalam. The word Varmam refers to static energy and the term Kaalam refers to kinetic energy.

Siddhars enumerate *'Naadi'* as a fundamental principle of art of varmam. According to Siddhars, the term *'Naadi'* is not applicable to just channels in which blood flows, but also extends to energy streams through which vital energy flows[6a]. The Varmam text called *'Kumbamuni Narambarai'* lists out 18 kinds of *Naadis*[6a]. Of these, twelve *Naadis* are considered medically important and are explained in most Varmam texts. Among them, three *Naadis* are given great emphasis when it comes to maintaining health. The knowledge about naadi is important for a *Varmam* physician to know the pathogenesis of disease and to give treatment.

Three naadis *Idakalai, Pingkalai, Suzhumunai* are important in the maintenance of homeostasis between *vatham, pitham kapham*. Any damage to the flow of these naadis results in a disease.

Table Showing the Padu Varmam directly linked to Naadi:

S. No	Varmam point	Naadi
1	Thilardha Kaalam	Suzhumunai Naadi
2	Natchathira Kaalam	Pingkalai Naadi
3	Pidari Kalam	Idakalai Naadi
4	Sevikutri	Singuvai
5	Urakka kaalam	Purudan
6	Thummi kaalam	Kaanthari
7	Ner varmam	Asani
8	Urumi kaalam	Karu
9	Adappa kaalam	Alampurudan
10	Siria athichurukki	Pasali
11	Valia athichurukki	Visulodharan
12	Kallidai kaalam	Sangini

Thus, a Varmam which is composed of energy track (Naadi), vital air (Vaayu) and basic pranan (Vaasi) should be elicited.

LOCATIONS OF VARMAM POINTS:

Varmam Points in the body can be determined by

a) Anatomical location

b) Proportional Measurement

c) Graphical measuring method

d) Locating by reference to adjacent Varmam points

e) Location by Classification

f) Finger breadth Measurement Method

g) Thread – measurement method.

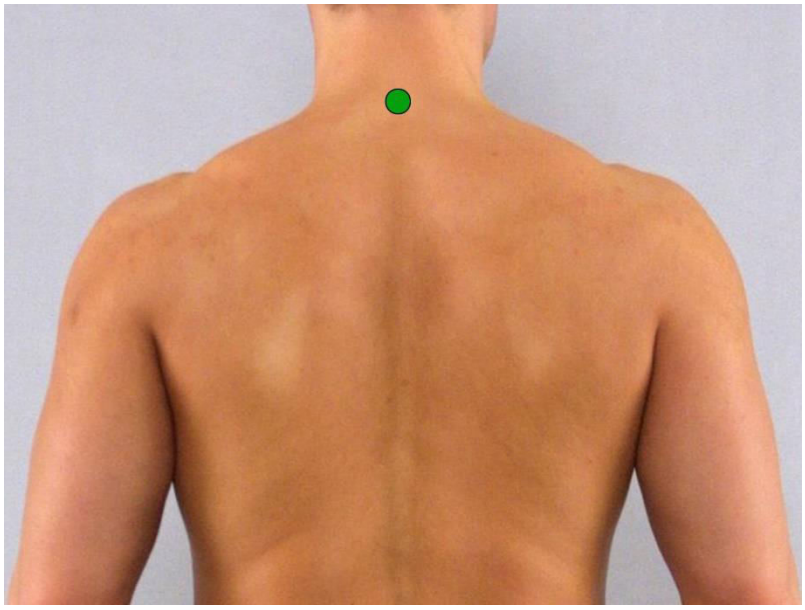
VARMAM STIMULATION FOR SAGANAVATHAM

1. Sara Mudichu Varmam:

“முடிச்சியப்பா கழுத்தடியில் புசம் நேராக
முன்னொளியாம் சரமுடிச்சி ஒன்று”

“இருப்பென்னும் கழுத்தினோடு தோள்
புஜம் சேரும்ஸ்தானம்
விருப்பென்னும் தண்டெலும்பில்
வலுக்கட்டும் நிலையம் இங்காகும்
உறுப்பெறும் தலைகழுத்து வலுகட்டும்
தன்மைஇங்கேயாம்.”

Location:



It is located at the back in the cervical prominence, at the C7-T1 junction.

2. Kakkattai kaalam:

“வளுவில்லா தோளிலிரு விரலருகில்
வன்மையுள்ள காக்கட்டை காலம்”

“மன்றான தொளில் இரண்டைங்குலமே நீங்கி
மருவுகின்ற தலமதிலே காக்கட்டை காலம்”

“பாரடா தொளிலிரு விரல்தான் நீங்கி
பரிவு காக்கட்டை யுடகாலமாகும்”

“சுமக்குமந்த தொள்தனலே நடுமையத்தில் காணூம் நீ
காக்கட்டை வர்மம் ஒன்று”

Location:

It is located in the supraclavicular fossa it reveals that kakattai kalam supplies energy and acts as an anchorage to the whole body below the neck and it helps in the movement of neck.

3. Manibantha varmam:

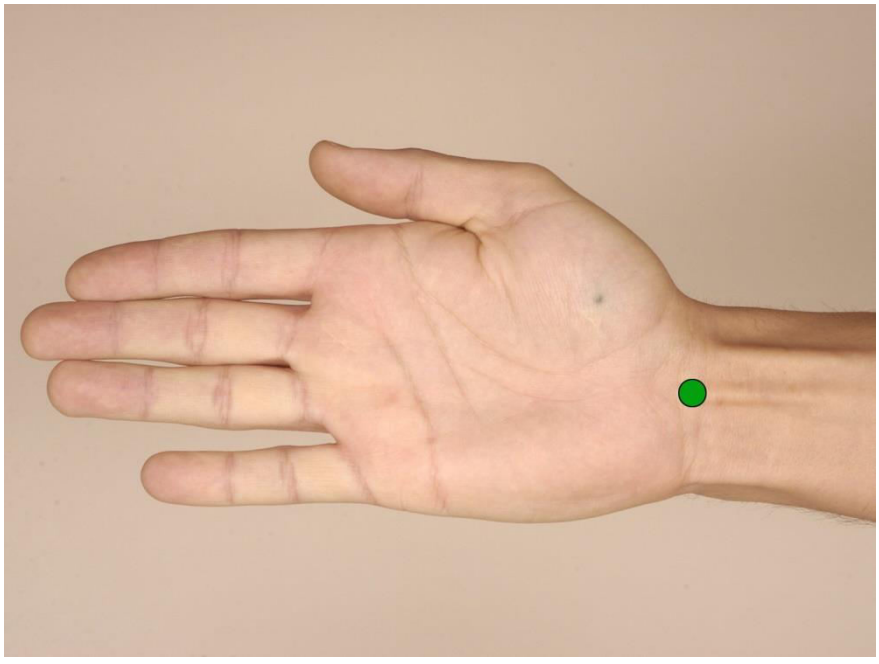
“விரியாத மணிக்கட்டில் மணிபந்தம்
வீரான விரல் நாலின்மேல் ஆந்தை வர்மம்”

“வன்முடிச்சியதின் கீழ் மணிக்கட்டு வர்மம்
சரியதினிலிருந்து எட்டு விரல் மேலே
தடவிப்பார் வஷமணிபந்த வர்மம்”

“மிகையதாம் மணிக்கெட்டாகும் இடத்திலே மணிபந்தம் பார்”

“முழைங்கையை பிடித்துக்கொண்டு
பிடிப்படி மணிக்கட்டில்தான் உடன்விடும்”

Location:



It is located in the middle of the wrist joint.

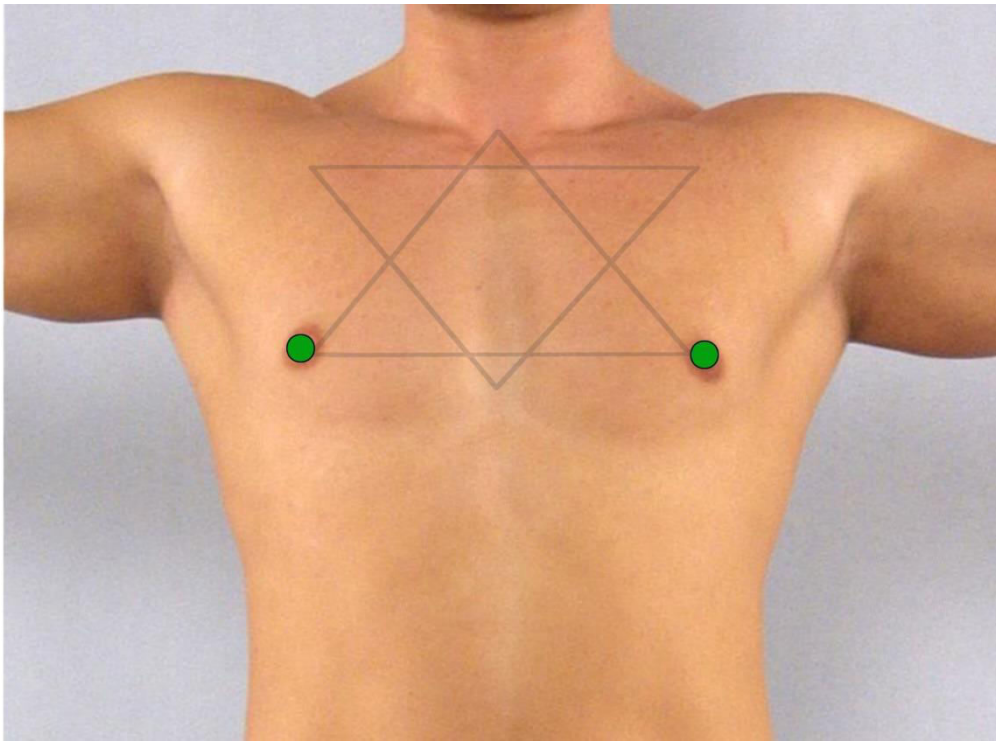
4. Thoosiga varmam:

“முலைக்கண்ணில் தூசுஷிக னிறைக் கீழ்....”

“‘நேரவே முலைக்கண்ணில் நிற்குமே தூசிகம் பார்
ஏரவே தூகிகத்தில் எட்டீரல் சுற்றியாமே”

“சூத்திர காலத்துக்கு கீழ் நான்கு விரலுக்குள் எட்டுமுக வர்மம்
முலைக் காம்பைச் சுற்றி வர்மங்கள் எட்டு”

Location:



It is located in the nipple and it helps in the movement of neck

5. kavuli kaalam:

“தானிதே கையிடைலில் கவளி தன்னில்

மானிதே பெருவிரலின் இடுக்கிலப்பா

மகத்தான இடுக்கு வர்மமிதர்கு பேரு”

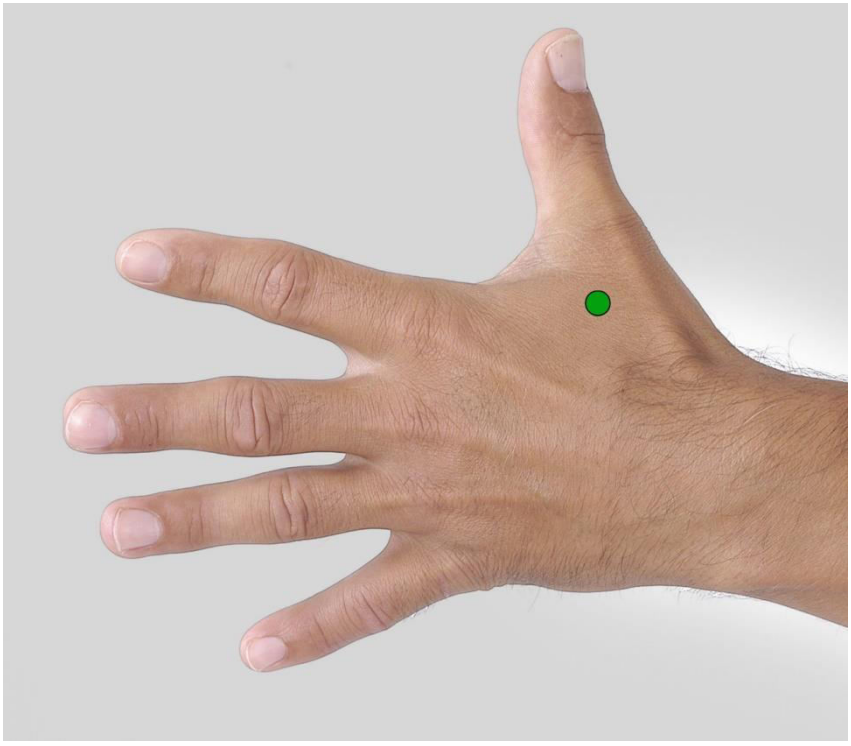
“கற்பமென்ன கையிடையில் கவுளிக்காலம்”

“புகழான கவுளிதனில் கவுளிவர்மம்”

“பெருவிரலிலிருந்து கைமணிக்கட்டு வரைக்கும் அளவெடுத்து

இரண்டாய் மடக்கினால் கவுளிகாலம் அறியலாம்”

Location:



It is located in the first web space between the thumb and index finger. It gives strength to shoulder joint.

MATERIALS AND METHODS

Approval of the Screening committee and Institutional ethical committee were obtained for undertaking the present study.

The study design and the underlying hypothesis and the rights to withdraw from the study at any time were informed orally and in writing to all the participants. A single center open clinical trial was undertaken in OPD of PG department of Varmam, Puramaruthuvam and Sirappu maruthuvam , Govt. Siddha medical college attached with Arignar Anna Hospital for Indian Medicine and homoeopathy, Arumbakkam, chennai-106 for a period from June 2017 to June 2018. 60 patients who fulfilled the inclusion criteria were included for the study.

Selection of cases:

Patients reporting at OPD of Arignar Anna Government Hospital of Indian Medicine, satisfying the inclusion and exclusion criteria were eligible for participation in the trial. They were included in the study with the approval of Head of the Department.

They were subjected to screening test and documented using screening Performa. 60 patients who fulfilled the inclusion criteria were subjected to protocol comprising selection criteria, clinical assessment, Siddha assessment, laboratory investigations, and diagnosis and treatment aspect.

Data collection forms:

- Form i - Screening and selection proforma
- Form ii -History taking proforma
- Form iii – Clinical assessment proforma
- Form iv: Laboratory investigations proforma
- Form v: Informed consent form

Inclusion criteria:

- Age: between 20 years and 60 years
- Sex: Both Male and Female

- Pain in the nape of the neck
- Cervical radiculopathy (If Spurling Test positive)
- With or without numbness in the upper limbs
- Giddiness and
- Neck stiffness

Exclusion Criteria

History of

- Trauma
- Spina bifida
- Congenital anomalies of spine
- Thoracic Outlet syndrome
- Diabetes mellitus
- Ankylosing spondylosis
- Tuberculosis in spine
- Cardiac diseases
- Pregnancy and lactation
- Neoplasms
- Patients with any other serious systemic illness

Withdrawal Criteria

1. Intolerance to the drug and development of any serious adverse effects during the trial (If ADR is reported the patient will be directed to RPC)
2. Patients turned unwilling to continue in the course of clinical trial
3. Poor compliance.
4. Any other acute illness which need rescue medication.

STUDY DESIGN

SELECTION OF TRIAL GROUPS:

Trial groups = 3 Groups I, II, III (20 Cases in each group)

As and when patients fulfilling all criterias visit the OPD

GROUP I : *Kurunthotti kashayam* 60 ml B.D for 21 days.

GROUP II : *Kurunthotti kashayam(Int) and Azhinjil Thylam*(Ext) for 21 days

GROUP III : Kurunthotti Kashayam (Int) & Azhinjil Thylam (Ext) and *Varmam* Therapy for 21 days.

STANDARD OPERATING PROCEDURE:

SOURCE OF RAW DRUGS:

The required raw drugs were purchased from authorized centers. The raw drugs were authenticated by the PG Gunapadam, GSMC, Chennai. Then the medicine was purified and prepared in Gunapadam laboratory of Government Siddha Medical College, Chennai-106.

LIST OF INGREDENTS: Kurunthotti Kashayam

S.No	Name of the ingredient	Botanical name
1	Sitramutti	Pavonia zeylanica
2	Amanakkuver	Ricinus comminus
3	Nochi ver	Vitex negunda
4	Sagasaraam ver	Ecbolium linneanum
5	Velluli	Allium sativam
6	Devatharu	Cedrus deodara
7	Sitrarathai	Alpinia officinarum
8	Perarathai	Alpinia galangal

PREPARATION OF THE DRUG:

1. Procurement/collection of ingredients for the preparation of Kurunthotti Kashayam.
2. Purification of ingredients for the above (Agathiar sarakku suthi muraigal)
3. Coarse powder mixture of the above was pocketted (70gms) quantity.

DRUG DOSAGE:

Patients who come under these treatment groups namely G1 and G2 &G3 were handed over a medicine packet and instructed to prepare kasayam.

Adjuvant : Inthuppu 1 gm.

Dosage : Orally daily 60 ml bid.

Kasayam preparation Method:

Approximately 5 gms were added to 120 ml of potable water and boiled to reduce into one fourth and take orally when it is lukewarm.

STANDARTISATION OF TRIAL DRUG:

The Prepared drug was submitted for conducting various standartisation procedures, as under

1. Toxicological studies (Annexure)
2. Pharmacological studies.
3. Physico-chemical analysis
4. Phytochemical analysis
5. Microbial pathogenicity
6. Antibacterial activity and
7. Heavy Metal analysis

VARMAM THERAPY

The following *Varmam points* will be given twice in a week for *Sagana vatham*:

- ***Sara Mudichu Varmam:***

  It is located at the back in the cervical prominence, at the C7-T1 junction. *(Varma Choodamani ennum Pancheekarana pinnal- 1500)*

- ***Kakkattai Kaalam***:

  It is located in the supraclavicular fossa.

  - *(Varma Laada Choothiram– 300)*

- ***Manibantha Varmam:***

  It is located in the middle of the wrist joint.

  - *(Varma Laada Choothiram– 300)*

- ***Kavuli Kaalam:***

  It is located in the first web space.

  - *(Varma Laada Choothiram– 300*

- ***Thoosigam Varmam:***

  It is located in the nipple.

  - *(Varma Laada Choothiram– 300)*

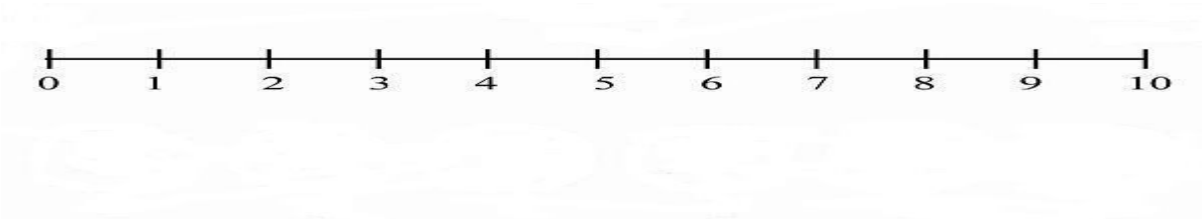
CRITERIA FOR OUTCOME ASSESSMENT:

Marked improvement	: Reduction of at least 5 points in Visual Analog Scale
Moderate improvement	: Reduction of more than 3-4 points in Visual Analog Scale
Mild improvement	: Reduction of 1-2 points in VAS
No improvement	: Reduction of 0 points / No reduction in Visual Analog Scale

TESTS AND ASSESMENTS:

1. CLINICAL ASSESMENTS

UNIVERSAL PAIN ASSESMENT SCALE



0 : No Pain, 1 -3 : Mild pain, 4-6 : Moderate pain and 7-10 : Severe pain

- Pain in nape of the neck – Universal pain scale
- Radiating pain in upper limbs - Spurling's test
- Tenderness, Numbness
- Stiffness of neck
- Restriction of movements of neck
- Giddiness

2. ROUTINE INVESTIGATIONS

1. Complete blood routine test.
    - TC,DC,ESR,HB and BS(R).
2. Urine analysis – Alb,sugar,deposits
3. Blood urea & serum creatinine.

3. RADIOLOGICAL INVESTIGATION

X-ray cervical spine AP and lat view

SIDDHA INVESTIGATION

En vagai thervugal

The cases were regarded in a prescribed Proforma prepared on the basis of siddha methodology. An individual case sheet was maintained for each case in the outpatient department.

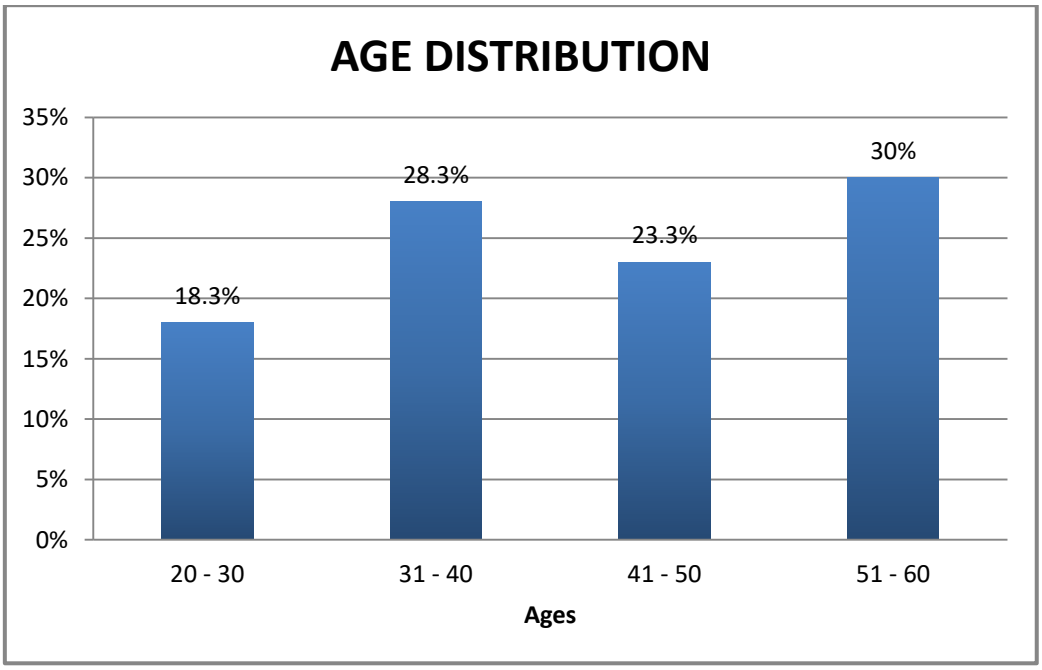
RESULTS AND OBSERVATIONS

Results of the study were observed with respect to the following criteria

1. Age distribution
2. Gender distribution
3. Occupational distribution
4. Socio-economic status
5. Diet
6. Duration of illness
7. Paruvakalangal
8. Thinaigal.
9. Paruva Kaalam (Season)
10. Disturbances in Vali
11. Disturbances in Azhal
12. Disturbances in Iyyam
13. Envagai thervugal
14. Naadi
15. Neikkuri
16. Clinical Prognosis
    - Group I
    - Group II
    - Group III

AGE DISTRIBUTION

S.No	Age	No of cases	Percentage
1	20-30	11	18.3
2	31-40	17	28.3
3	41-50	14	23.3
4	51-60	18	30

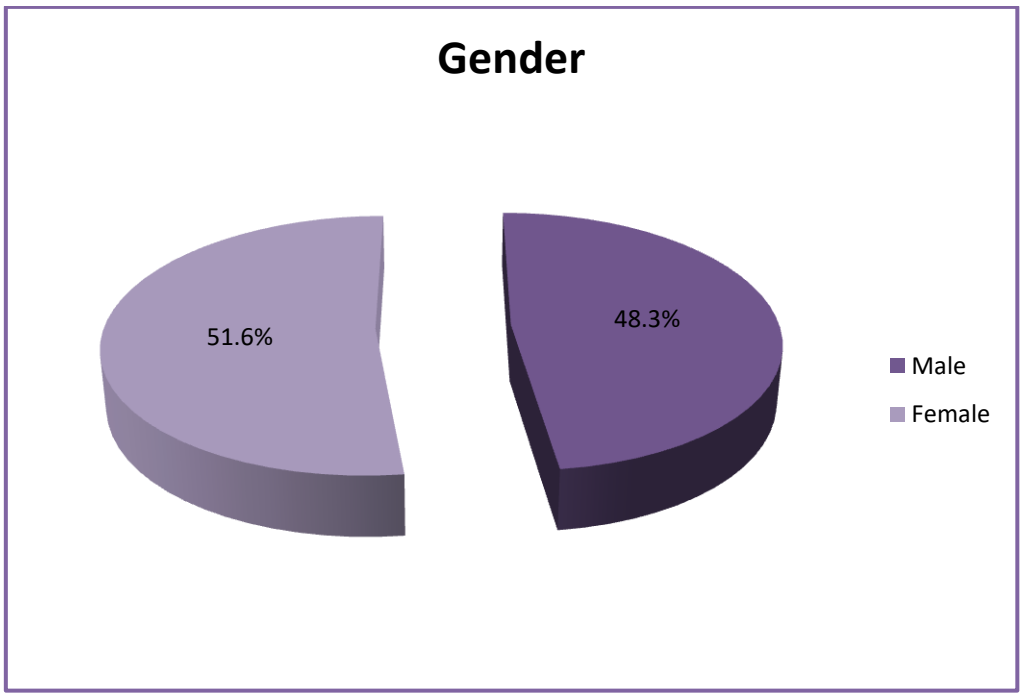


Inference:

Among 60 cases, 18.3% of cases were in the age group of 20-30, 28.3 %, 23.3%, and 30% of cases were in the age of 31-40, 41-50 and 51-60 respectively.

GENDER

S.No	Gender	No of Cases	Percentage
1.	Male	29	48.3
2.	Female	31	51.6

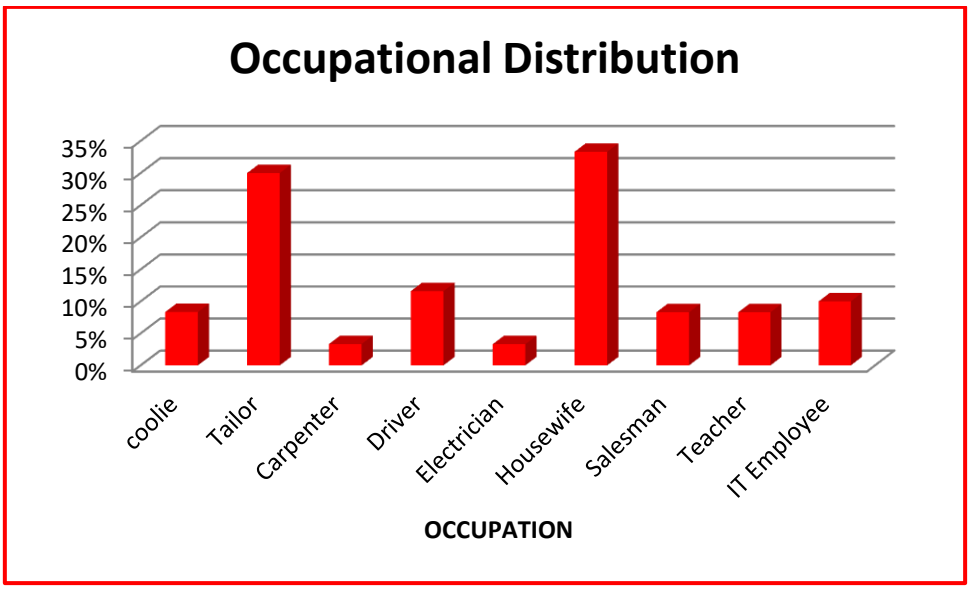


Inference:

Among 60 cases, 48.3% of cases were Males and 48.3% of patients were females.

OCCUPATIONAL DISTRIBUTION

Occupation	No of cases	Percentage
Coolie	5	8%
Tailor	18	30%
Carpenter	2	3%
Driver	7	12%
Electrician	2	3%
House wife	20	33%
Salesman	5	8%
Teacher	5	8%
IT Employee	6	10%

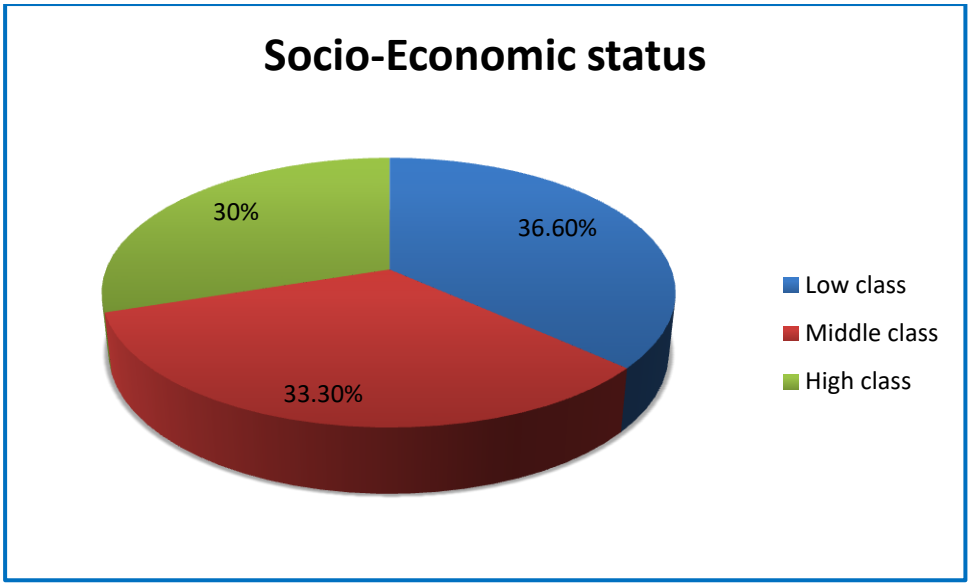


INFERENCE:

Among 60 cases, 33% of cases were House wives, 30% of cases were Tailors, 12% were Drivers, 10% of cases were IT employees. Coolie, Salesmen and Teachers were 8% each. Carpenters and Electricians were 3% each.

SOCIO ECONOMIC STATUS

Socio economic status	No of Patients	Percentage
Low Income Group	22	36.6%
Middle Income Group	20	33.3%
High Income Group	18	30%

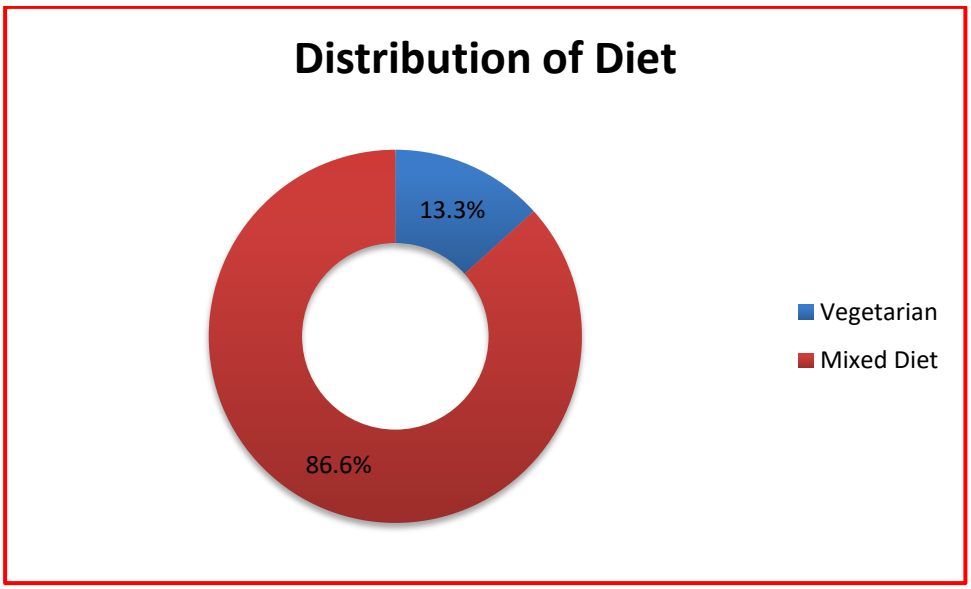


INFERENCE:

Among 60 patients, 36.6%, 33.3% and 30% of cases belong to Low, middle and High income category respectively.

DISTRIBUTION OF DIET

Diet	No of Patients	Percentage
Vegetarian	8	13%
Mixed Diet	52	86%

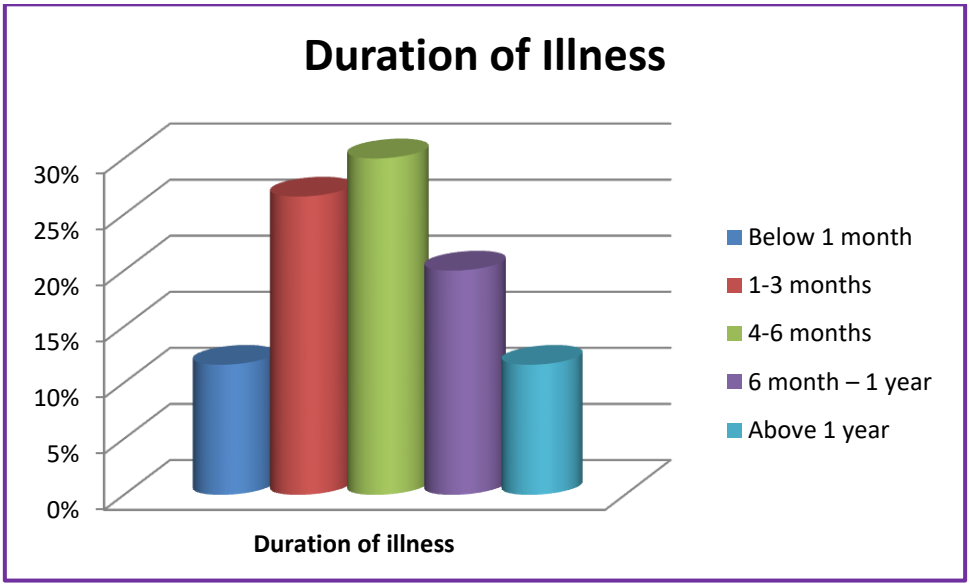


INFERENCE

Among 60 cases, 86.6% of cases were consuming mixed diet and 13.3% were Vegetarian

DURATION OF ILLNESS

Duration of illness	No of Patients	Percentage
Below 1 month	7	11.6
1-3 months	16	26.6
4-6 months	18	30
6 month – 1 year	12	20
Above 1 year	7	11.6

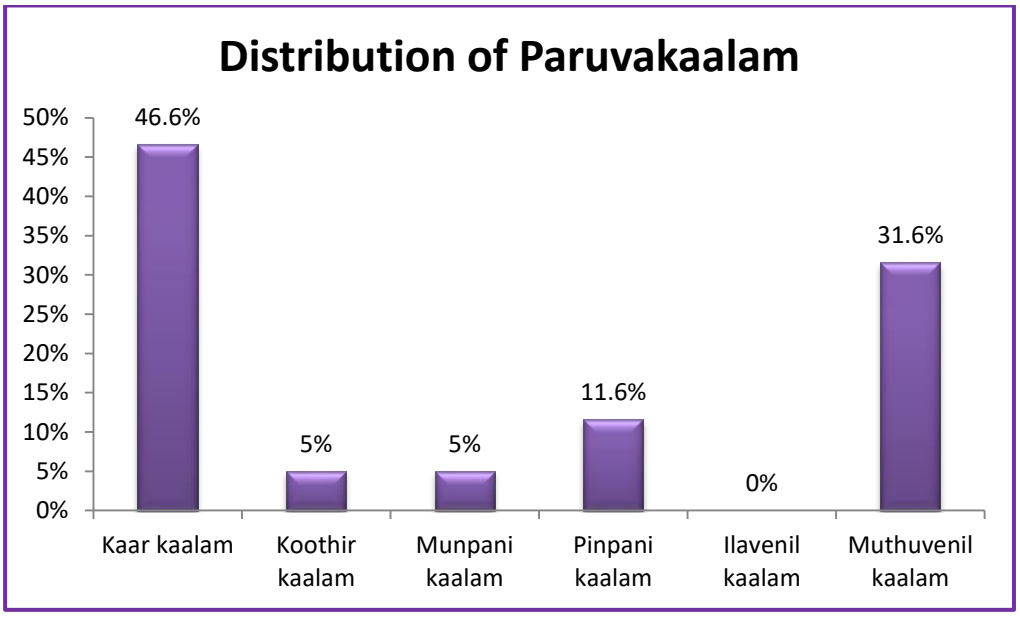


INFERENCE:

Out of 60 patients subjected in the present study, 11.6% belonged to less than 1 month of illness and others were 26.6% in 1-3 months, 30% in 4-6 months, 20% in 6 month – 1year and 11.6% in 1 year of illness.

DISTRIBUTION AMONG PARUVAKAALANGAL

S.No	Paruvakaalam	No of cases	Percentage
1.	Kaar kaalam	28	46.6
2.	Koothir kaalam	3	5
3.	Munpani kaalam	3	5
4.	Pinpani kaalam	7	11.6
5.	Ilavenil kaalam	0	0
6.	Muthuvenil kaalam	19	31.6

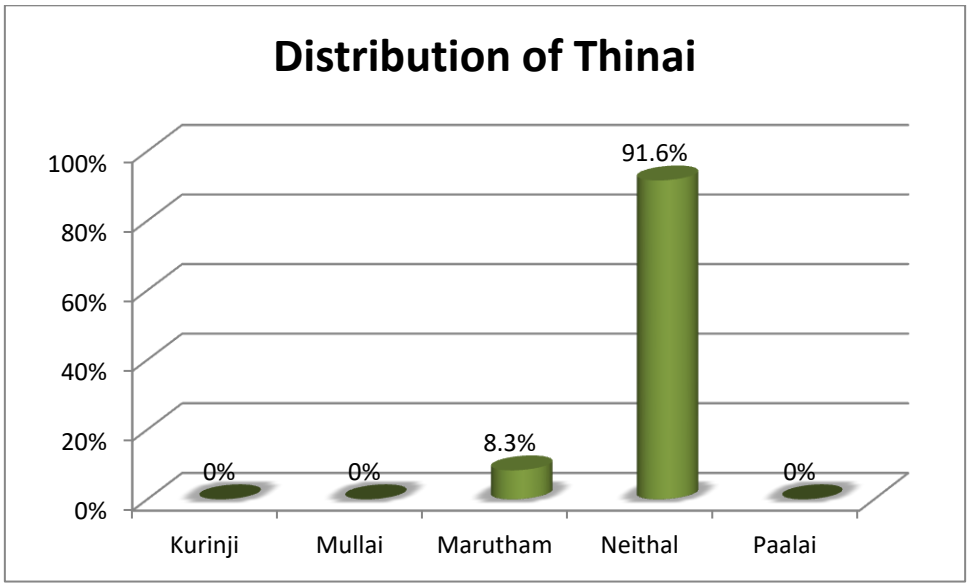


INFERENCE:

Among 60 patients, 46.6%, 5%, 5%, 11.6% and 31.6% of patients came in Kaar, koothir, Munipani, Pinpani and Muthuvenil kaalam. No cases were came in Ilavenil kaalam.

DISTRIBUTION AMONG THINAI

S.No	Thinai	No of Patients	Percentage
1	Kurinji	0	0
2	Mullai	0	0
3	Marutham	5	8.3
4	Neithal	55	91.6
5	Paalai	0	0

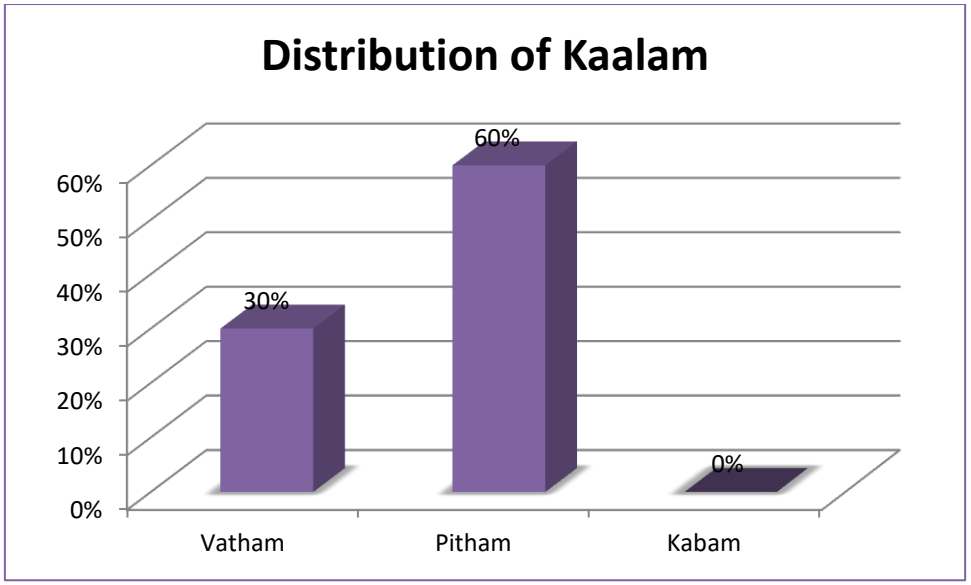


INFERENCE:

Out of 60 patients, 91.6% of patients belongs to Neithal Nilam and 8.3% of patietns belong to Marutha Nilam

DISTRIBUTION AMONG KAALAM

S.No	Kaalam	No of patients	Percentage
1	Vatham	18	30
2	Pitham	42	60
3	Kabam	0	0

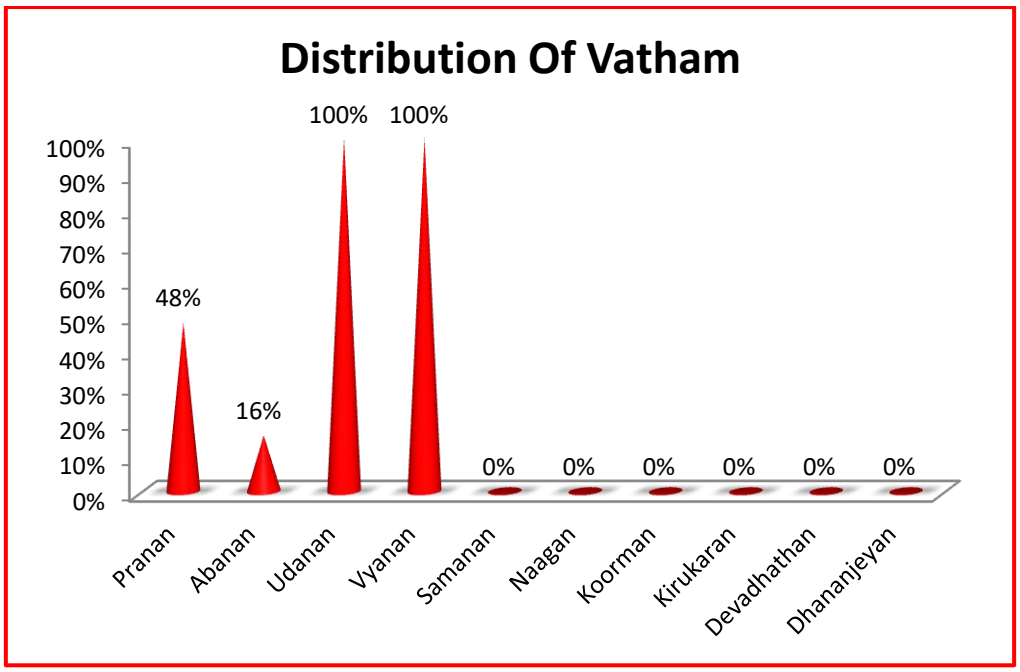


INFERENCE:

Out of 60 patients, 30% of patients were belonged Vatha kaalam and 60% belonged to Pitha kaalam.

DISTRIBUTION OF VATHAM

Vatham	No of Patients	Percentage
Pranan	0	0
Abanan	29	48
Udanan	10	16
Vyanan	60	100
Samanan	60	100
Naagan	0	0
Koorman	0	0
Kirukaran	0	0
Devadhathan	0	0
Dhananjeyan	-	-

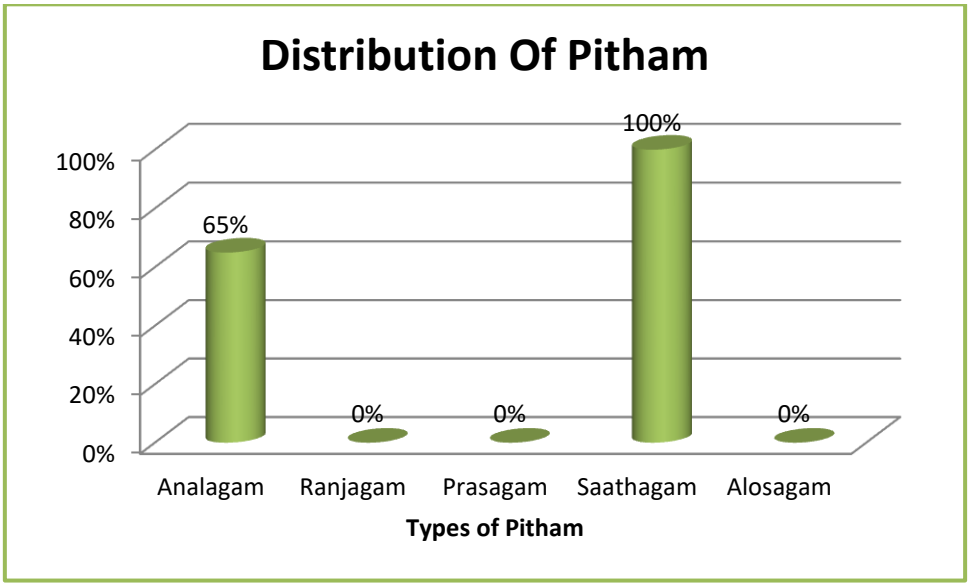


INFERENCE:

Out of 60 Patients, Udanan and Samanan were affected in all the patients. Pranan and abanan were affected in 48% and 16% of patients respectively.

DISTRIBUTION OF PITHAM

S.No	Pitham	No of Patients	Percentage
1	Analagam	39	65
2	Ranjagam	0	0
3	Prasagam	0	0
4	Saathagam	60	100
5	Alosagam	0	0

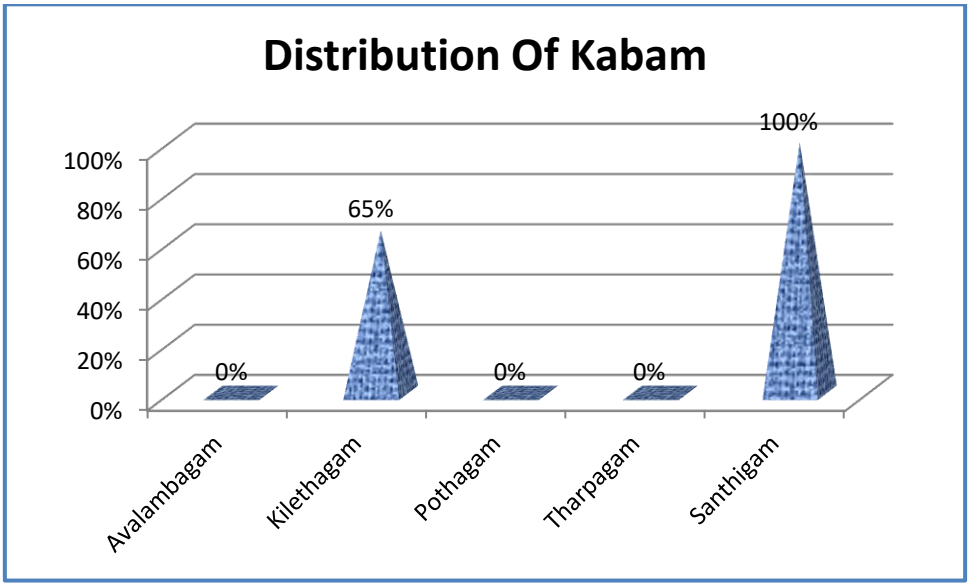


INFERENCE:

Out of 60 patients, Anarpitham was affected in 65% of patients and Saathaga pitham was affected in all the patients (100%).

DISTRIBUTION OF KABAM

S.No	Kabam	No of Patients	Percentage
1	Avalambagam	0	0
2	Kilethagam	39	65
3	Pothagam	0	0
4	Tharpagam	0	0
5	Santhigam	60	100

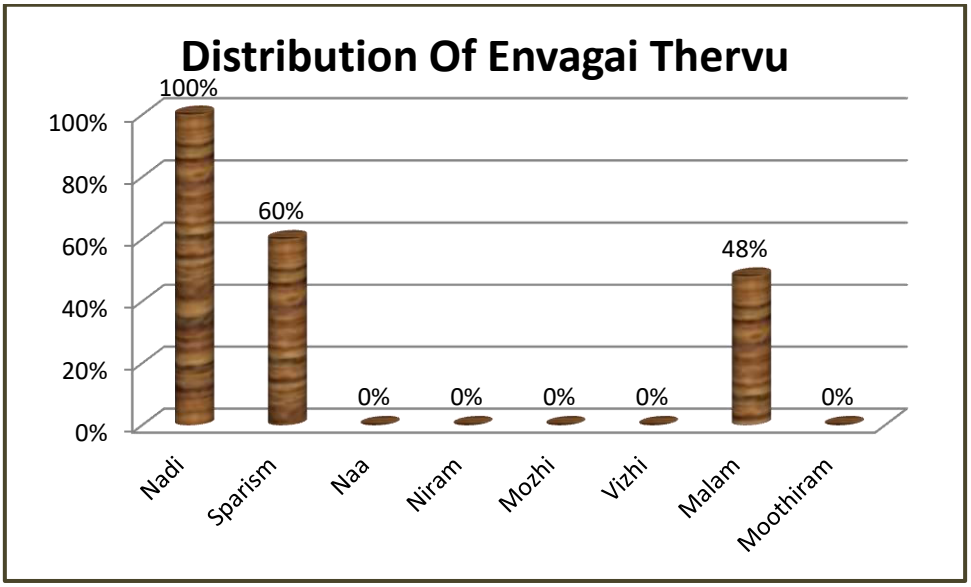


INFERENCE:

Out of 60 patients, Santhigam was affected in all patients (100%) and Kilethagam was affected in 65% of patients.

DISTRIBUTION OF ENVAGAI THERVU

S.No	Envagaithervu	No of Patients	Percentage
1	Nadi	60	100
2	Sparism	36	60
3	Naa	0	0
4	Niram	0	0
5	Mozhi	0	0
6	Vizhi	0	0
7	Malam	29	48
8	Moothiram	0	0

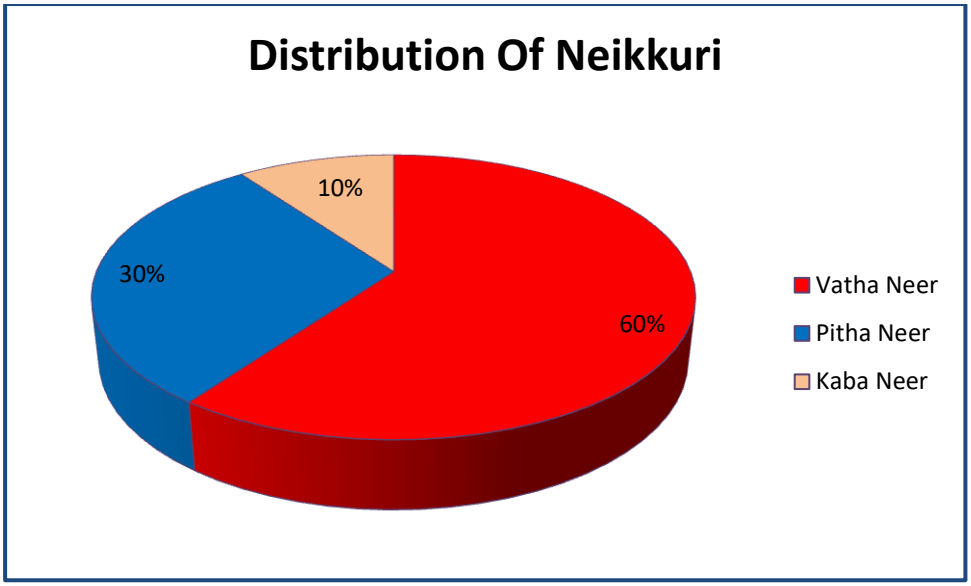


INFERENCE:

Out of 60 patients, Nadi was affected in100% of patients, Sparism was affected in 60% of patients and Malam was affected in48% of patients.

NEIKKURI

S.No	Neikkuri	No of Cases	Percentage
1	Vatha Neer	36	60
2	Pitha Neer	18	30
3	Kaba Neer	06	10

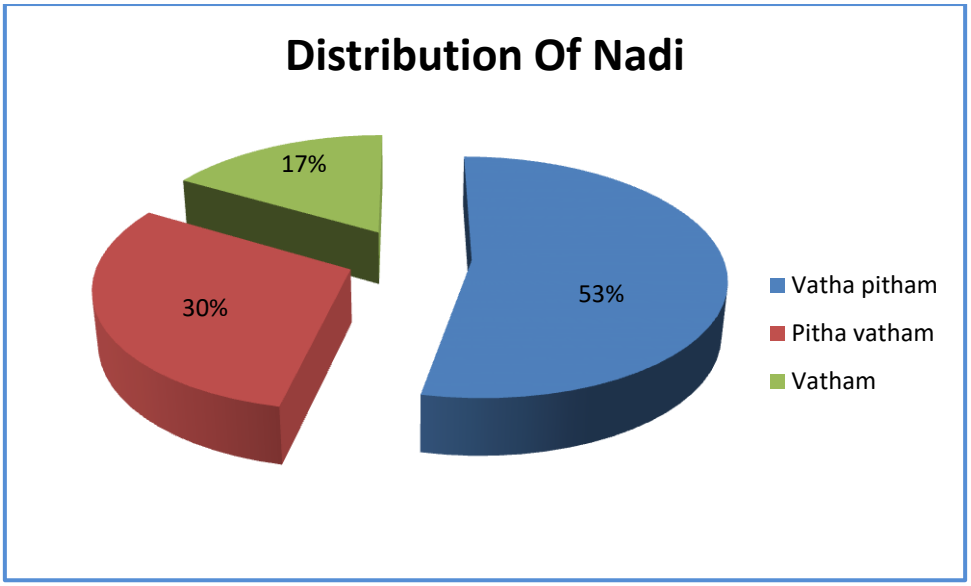


INFERENCE:

Out of 60 patient's urine sample vatha neer was present in 60% of patient's urine sample, Pitha neer was present in 30% of patient's urine sample and Kaba neer was present in 10% of urine sample.

DISTRIBUTION OF NADI

S.No	Nadi	No of cases	Percentage
1	Vatha pitham	32	53.3
2	Pitha vatham	18	30
3	Vatham	10	16.6

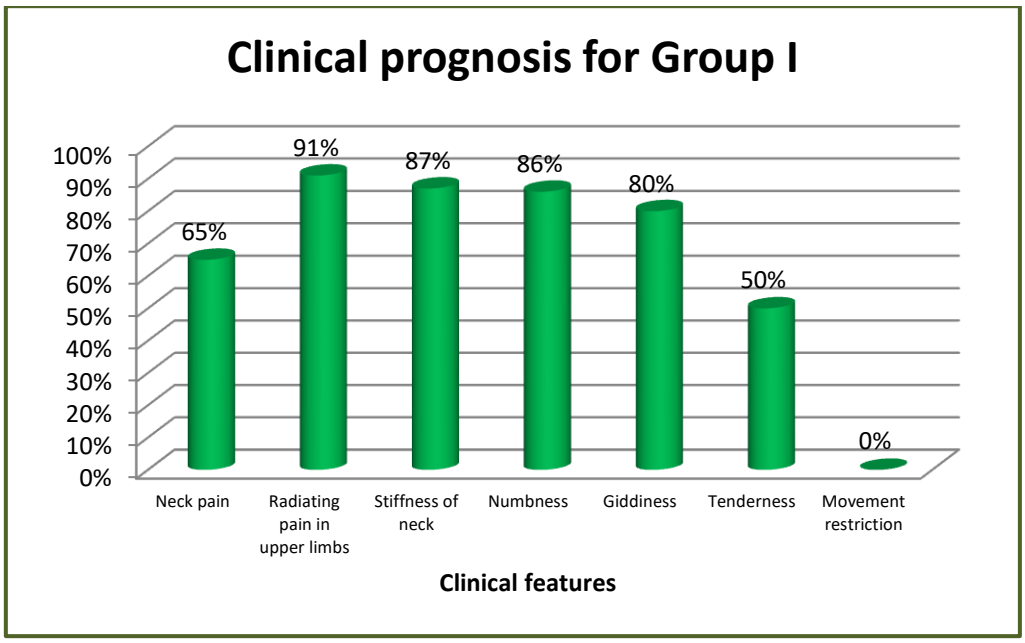


INFERENCE:

Out of 60 patients, Vatha pitha nadi, Pitha vatha nadi and vatha nadi were present in 53%, 30% and 17% of patients.

Improvement in subjects treated with Internal medicine (Group I)

S.No	Clinical features	Before Treatment	After Treatment	Percentage of Response
1.	Neck pain	20	7	65%
2.	Radiating pain in upper limbs	11	1	91%
3.	Stiffness of neck	8	1	87%
4.	Numbness	7	1	86%
5.	Giddiness	5	1	80%
6.	Tenderness	4	2	50%
7.	Movement restriction	1	1	0%
8.	Overall response			66%

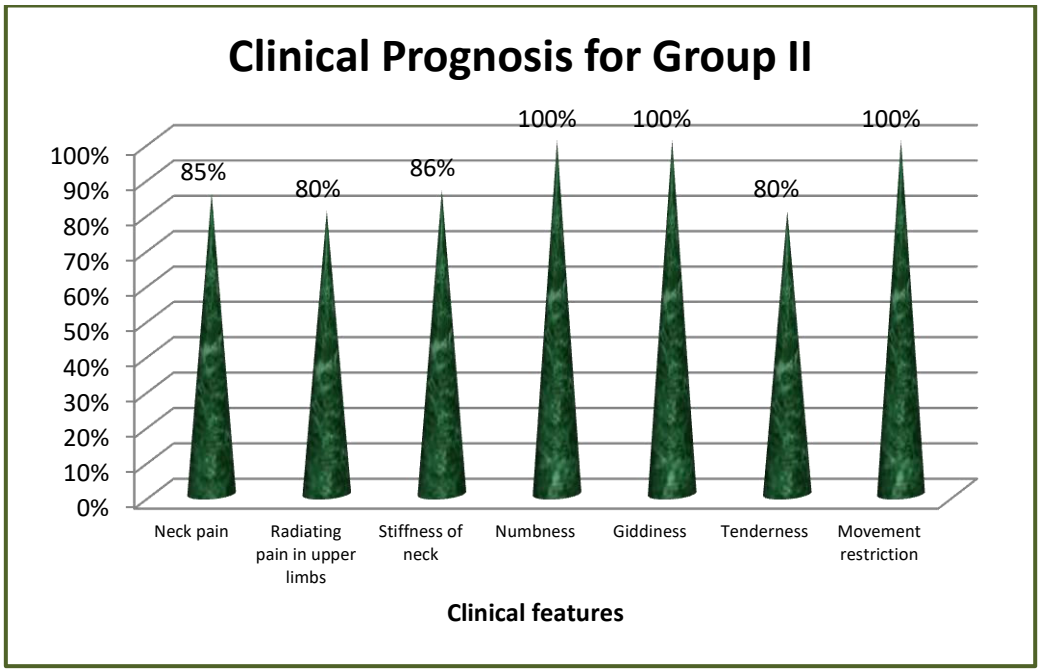


Inference:

65% of patients were relieved from Neck pain completely, 91%, of patients were relieved from Radiating pain in upper limbs. 87%, 86%, 80%, 50% and 0% of patients were relieved fromNeck stiffness, Numbness, Numbness, Giddiness, Tenderness and Movement restriction respectively.

Improvement in subjects treated with Internal & External Medicine only (Group 2)

S.No	Clinical features	Before Treatment	After Treatment	Percentage of Response
1.	Neck pain	20	3	85%
2.	Radiating pain in upper limbs	10	2	80%
3.	Stiffness of neck	7	1	86%
4.	Numbness	7	0	100%
5.	Giddiness	4	0	100%
6.	Tenderness	5	1	80%
7.	Movement restriction	1	0	100%
8.	Overall response			90%

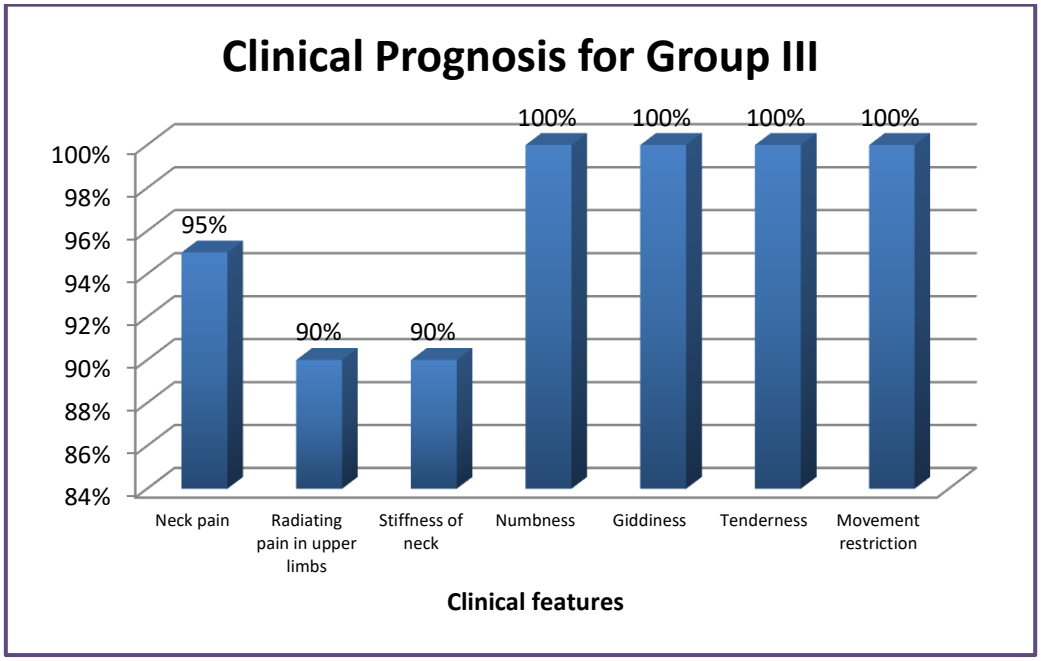


Inference:

85% of patients were relieved from Neck pain completely, 80%, of patients were relieved from Radiating pain in upper limbs. 86% and 80% of patients were relieved from Neck stiffness and Tenderness respectively. 100% of patients were relieved from Numbness, Giddiness and Movement restriction.

Improvement in subjects treated with Internal, External & Varmam therapy (Group 3)

S.No	Clinical features	Before Treatment	After Treatment	Percentage of Response
1.	Neck pain	20	1	95%
2.	Radiating pain in upper limbs	10	1	90%
3.	Stiffness of neck	10	1	90%
4.	Numbness	7	0	100%
5.	Giddiness	5	0	100%
6.	Tenderness	4	0	100%
7.	Movement restriction	2	0	100%
8.	Overall response			96%

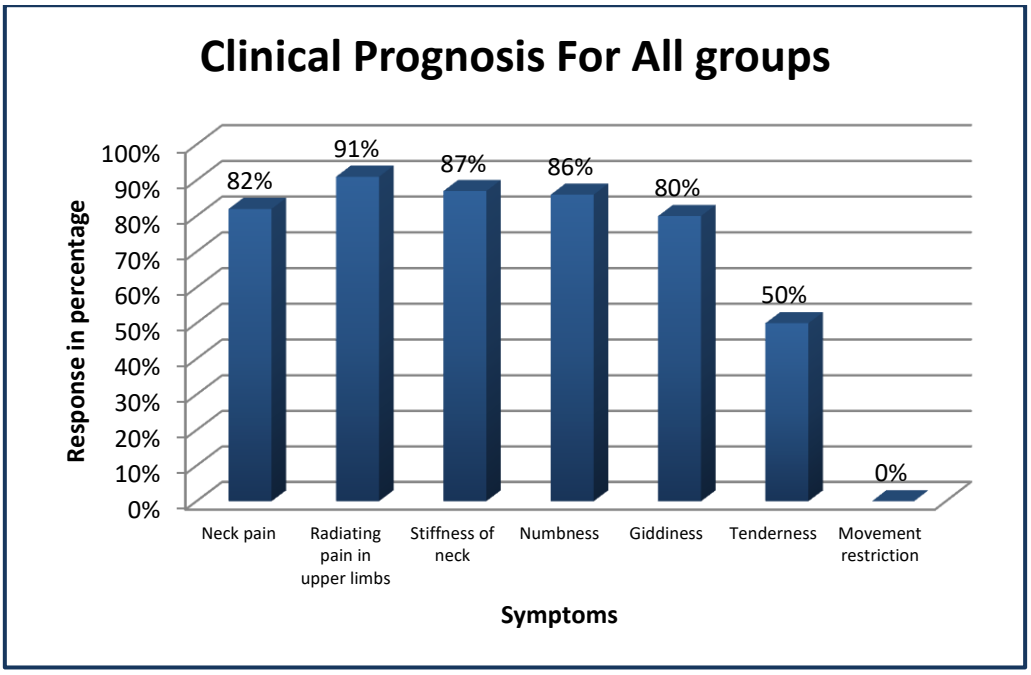


Inference:

100% of patients were relieved from Numbness, Giddiness, Tenderness and Movement restriction. 95% of Patients were relieved from Neck Pain. Radiating pain and Neck stiffness was relieved for 90 % of patients.

Clinical prognosis based on Symptoms (All Groups)

S.No	Clinical features	Before Treatment	After Treatment	Percentage of Response
1.	Neck pain	60	11	82%
2.	Radiating pain in upper limbs	31	4	87%
3.	Stiffness of neck	25	3	88%
4.	Numbness	21	1	95%
5.	Giddiness	14	1	93%
6.	Tenderness	13	3	76%
7.	Movement restriction	4	1	75%



INFERENCE:

92% of patients were relieved from Neck pain completely, 87%, of patients were relieved from Radiating pain in upper limbs. 88%, 95%, 93%, 76% and75% of patients were relieved fromNeck stiffness, Numbness, Numbness, Giddiness, Tenderness and Movement restriction respectively.

PAIN ASSESSMENT BASED ON VISUAL ANALOG SCALE –GROUP I

S.No	BT	AT	Difference	Prognosis
1	6	0	6	Good
2	8	6	2	Mild
3	6	0	6	Good
4	6	0	6	Good
5	10	8	2	Mild
6	8	0	8	Good
7	6	0	6	Good
8	4	0	4	Moderate
9	6	0	6	Good
10	7	0	7	Good
11	8	2	6	Good
12	9	8	1	Mild
13	10	7	3	Moderate
14	8	0	8	Good
15	6	6	0	No
16	6	0	6	Good
17	9	0	9	Good
18	8	4	4	Moderate
19	6	0	6	Good
20	7	0	7	Good

Note:

Improvement **Change of points in VAS**

Good improvement : > 5 points

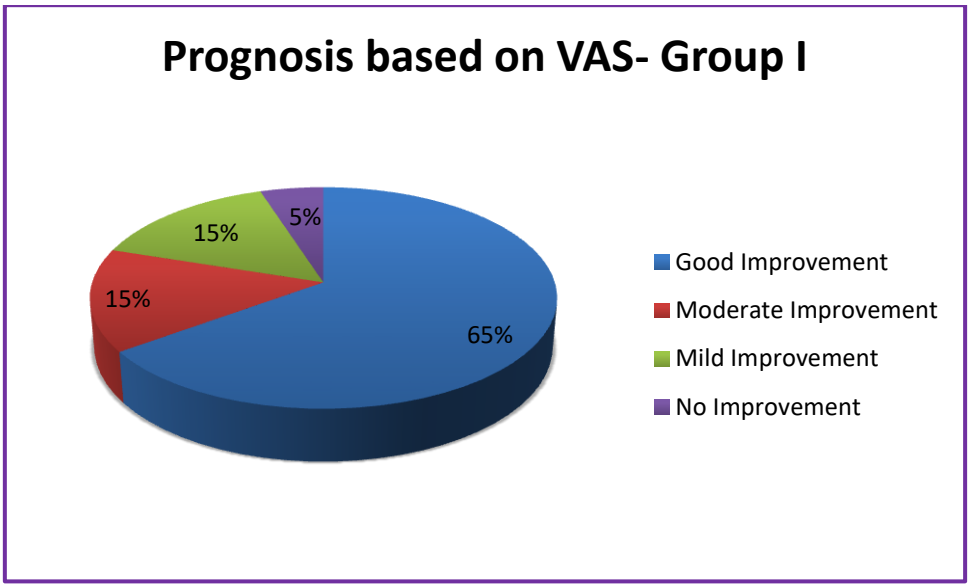
Moderate improvement : 3-5 points

Mild improvement : 1-2 points

No improvement : 0 points

RESULTS BASED ON VISUAL ANALOG SCALE - GROUP I

Prognosis	No of Patients	Percentage
Good Improvement	13	65%
Moderate Improvement	3	15%
Mild Improvement	3	15%
No Improvement	1	5%



Inference:

In Group I, 65% of patients had Good improvement, 15% of patients had moderate and mild improvement each and 5% of patients had No improvement.

PAIN ASSESSMENT BASED ON VISUAL ANALOG SCALE –GROUP II

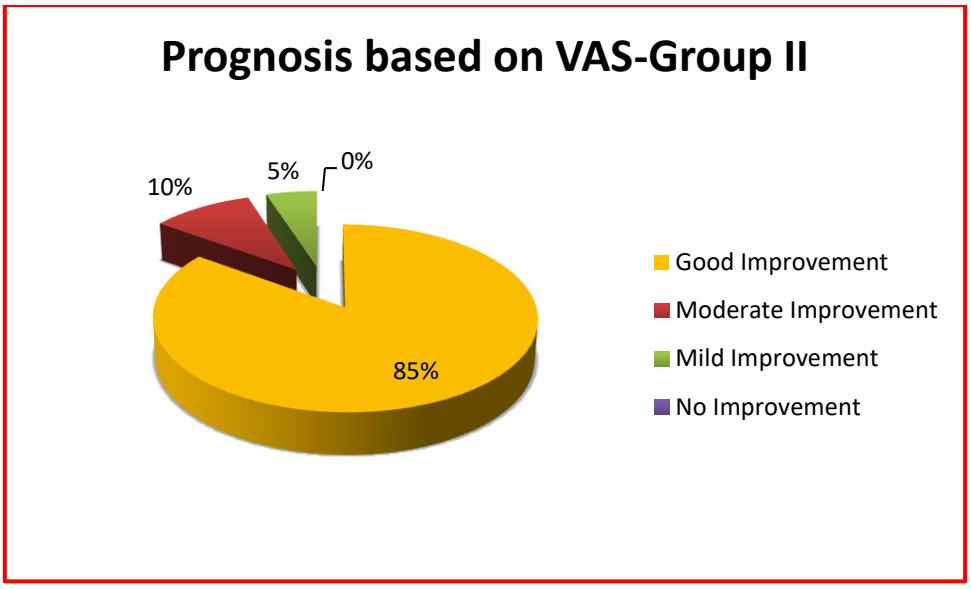
S.No	BT	AT	Difference	Prognosis
01	8	0	8	Good
02	7	0	7	Good
03	9	0	9	Good
04	10	0	10	Good
05	6	0	6	Good
06	8	0	8	Good
07	8	0	8	Good
08	6	0	6	Good
09	9	5	4	Moderate
10	6	0	6	Good
11	7	0	7	Good
12	6	0	6	Good
13	6	0	6	Good
14	6	0	6	Good
15	7	0	7	Good
16	8	0	8	Good
17	9	0	9	Good
18	6	0	6	Good
19	10	8	2	Mild
20	4	0	4	Moderate

Note:

Improvement	**Change of points in VAS**
Good improvement	: > 5 points
Moderate improvement	: 3-5 points
Mild improvement	: 1-2 points
No improvement	: 0 points

RESULTS BASED ON VISUAL ANALOG SCALE - GROUP II

Prognosis	No of Patients	Percentage
Good Improvement	17	85%
Moderate Improvement	2	10%
Mild Improvement	1	5%
No Improvement	0	0%



Inference:

In Group II, 85% of patients had Good improvement, 10% of patients had moderate improvement and 5% of the patients showed Mild improvement. No patients showed No improvement.

PAIN ASSESSMENT BASED ON VISUAL ANALOG SCALE – GROUP III

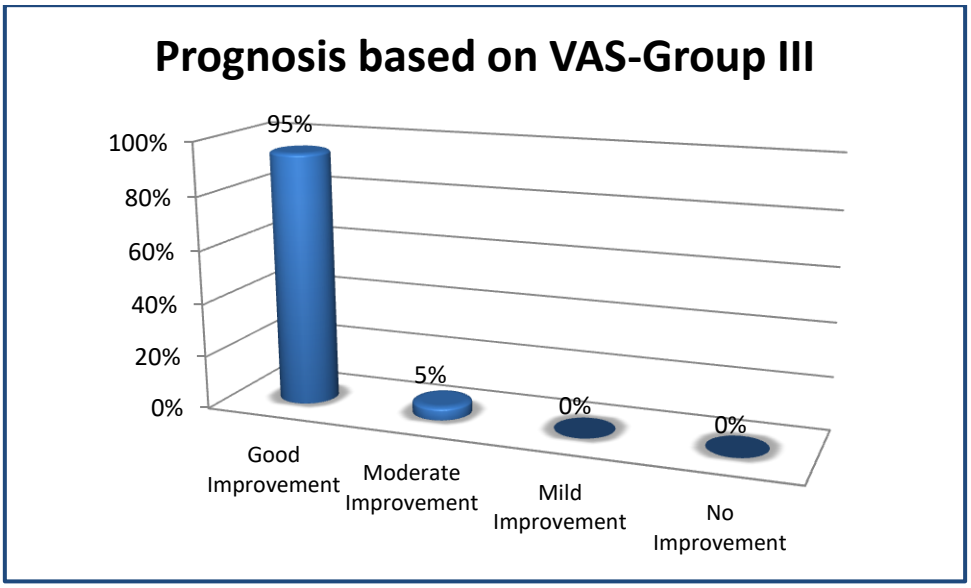
S. No	BT	AT	Difference	Prognosis
01	6	0	6	Good
02	8	0	8	Good
03	9	0	9	Good
04	9	0	9	Good
05	6	0	6	Good
06	8	0	8	Good
07	9	0	9	Good
08	4	0	4	Moderate
09	6	0	6	Good
10	8	0	8	Good
11	10	0	10	Good
12	8	0	8	Good
13	9	0	9	Good
14	7	0	7	Good
15	6	0	6	Good
16	9	0	9	Good
17	8	0	8	Good
18	6	0	6	Good
19	9	0	9	Good
20	6	0	6	Good

Note:

Improvement	**Change of points in VAS**
Good improvement	: > 5 points
Moderate improvement	: 3-5 points
Mild improvement	: 1-2 points
No improvement	: 0 points

RESULTS BASED ON VISUAL ANALOG SCALE - GROUP III

Prognosis	No of Patients	Percentage
Good Improvement	19	95%
Moderate Improvement	1	5%
Mild Improvement	0	0%
No Improvement	0	0%

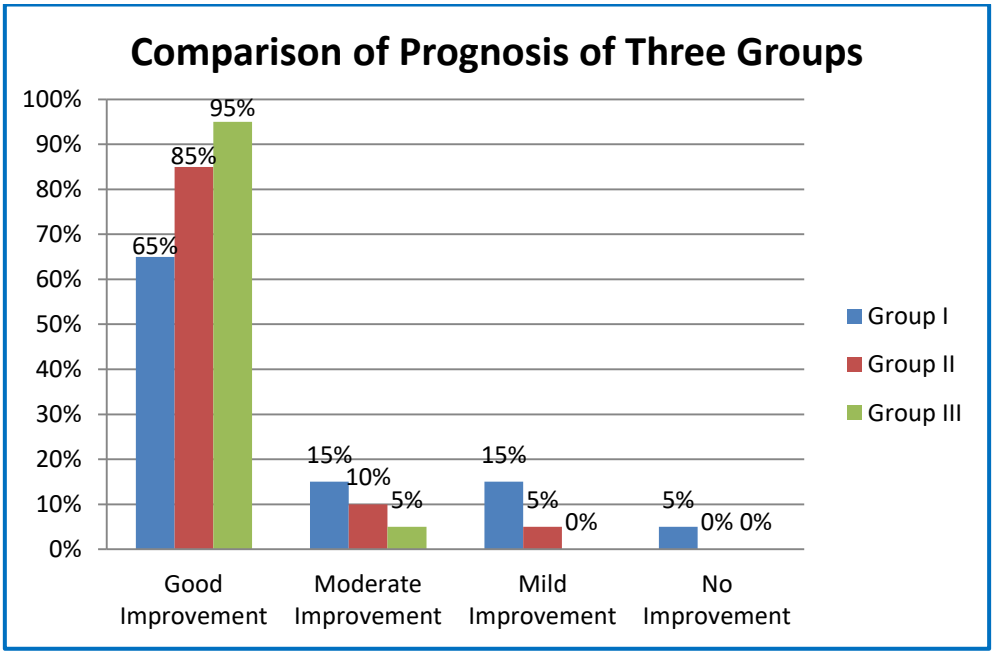


Inference:

In Group III, 95% of patients had Good improvement, 5% of patients had moderate improvement. None of the patients showed Mild and No improvement.

COMPARISION OF PROGNOSIS OF THREE TREATMENT GROUPS BASED ON VISUAL ANALOG SCALE

Prognosis	Group I	Group II	Group III
Good Improvement	65%	85%	95%
Moderate Improvement	15%	10%	5%
Mild Improvement	15%	5%	0%
No Improvement	5%	0%	0%



INFERENCE:

On comparing the three treatment groups Group III had shown better prognosis with 95% Good improvement and 5% Moderate improvement than the other treatment groups.

Treatment details of Subjective parameters of Group 1:

S.NO	OP NO	Name	Age/ Sex	Occupation	Duration of illness	Date of starting treatment	Date of withdrawal treatment	Results
01	7785	Pavithra	20/F	Tailor	4 months	17-7-2017	7-8-2017	Good Improvement
02	7833	Roslin devi	38/F	Tailor	5 months	17-7-2017	7-8-2017	Mild Improvement
03	8088	Gangammal	54/F	Coolie	3 months	18-7-2017	8-8-2017	Good Improvement
04	8509	Sheek	40/M	Driver	8 months	19-7-2017	9-8-2017	Good Improvement
05	8629	Vijay selvam	55/M	Salesman	6 months	20-7-2017	10-8-2017	Mild Improvement
06	9045	Sathyadevi	29/F	Housewife	3 months	21-7-2017	11-8-2017	Good Improvement
07	9745	Mohan	50/M	Electrician	1 year	24-7-2017	14-8-2017	Good Improvement
08	9728	Uma	49/F	Teacher	8 months	24-7-2017	14-8-2017	Moderate Improvement
09	73	Nagamma	37/F	Tailor	4 months	25-7-2017	15-8-2017	Good Improvement
10	405	Balaji	45/M	Driver	7 months	26-7-2017	16-8-2017	Good Improvement
11	446	Bhanumathi	52/F	Housewife	5 months	26-7-2017	16-8-2017	Good Improvement
12	2266	Jayaraman	52/M	Electrician	3 months	1-8-2017	22-8-2017	Mild Improvement
13	2029	Krishna Moorthy	44/M	Carpenter	6 months	1-8-2017	22-8-2017	Moderate Improvement
14	2266	Jayaraman	52/M	Driver	4 months	1-8-2017	22-8-2017	Good Improvement
15	932	Devi	35/F	Housewife	2 months	8-8-2017	29-8-2017	No Improvement
16	649	Nanda kumar	51/M	Tailor	3 months	15-8-2017	5-9-2017	Good Improvement
17	2671	Meera	60/F	Housewife	6 months	17-8-2017	7-9-2017	Good Improvement
18	7987	Vijayakumar	26/M	Teacher	3 months	20-8-2017	10-9-2017	Moderate Improvement
19	771	Gunaseelan	29/M	IT sector	4 months	22-8-2017	12-9-2017	Good Improvement
20	3632	Kalaimani	49/F	Tailor	6 months	24-8-2017	14-9-2017	Good Improvement

Treatment details of Subjective parameters of Group 1:

S.NO	OP No	Name	Age/ Sex	Occupation	Duration of illness	Date of starting treatment	Date of withdrawal treatment	Results
01	1075	Usha	30/F	Tailor	8 months	17-8-2017	07-9-2017	Good Improvement
02	7901	Ramalingam	56/M	Driver	6 months	17-8-2017	07-9-2017	Good Improvement
03	480	Sindu	26/F	House wife	4 months	24-8-2017	14-9-2017	Good Improvement
04	4902	Anuradha	38/F	Tailor	8 months	29-8-2017	19-9-2017	Good Improvement
05	5574	Kalaiarasi	30/F	Coolie	3 months	30-8-2017	20-9-2017	Good Improvement
06	9728	Perumal	49/M	Sales man	6 months	01-9-2017	22-9-2017	Good Improvement
07	2630	Ragasudha	42/F	Tailor	5 months	5-9-2017	26-9-2017	Good Improvement
08	9998	Govindarajan	58/M	Driver	1 year	7-9-2017	28-9-2017	Good Improvement
09	4997	Eshwar	34/M	Coolie	6 months	12-9-2017	3-10-2017	Moderate Improvement
10	539	Meenakshi	39/F	Tailor	8 months	14-9-2017	5-10-2017	Good Improvement
11	9986	Samudhrakani	46/M	Teacher	9 months	15-9-2017	6-10-2017	Good Improvement
12	5322	Lakshmi	58/F	House wife	1 year	19-9-2017	10-10-2017	Good Improvement
13	481	Rani	40/F	House wife	5 months	22-9-2017	13-10-2017	Good Improvement
14	9384	Duraisamy	51/M	Tailor	7 months	27-9-2017	18-10-2017	Good Improvement
15	2841	Menaka	47/F	Tailor	10 months	29-9-2017	20-10-2017	Good Improvement
16	2861	Parthasarathy	27/M	ITsector	2 months	3-10-2017	24-10-2017	Good Improvement
17	3360	Baghyalakshmi	32/F	Teacher	4 months	6-10-2017	27-10-2017	Good Improvement
18	3445	Thirunavukarasu	36/M	Tailor	6 months	10-10-2017	31-10-2017	Good Improvement
19	1234	Manigandan	25/M	Sales man	4 months	17-10-2017	7-11-2017	Mild Improvement
20	158	Kalaivani	32/F	ITsector	5 months	23-10-2017	13-11-2017	Moderate Improvement

Treatment details of Subjective parameters of Group 1:

S.NO	OP NO	Name	Age/ Sex	Occupation	Duration of illness	Date of starting treatment	Date of withdrawal treatment	Results
01	2563	Sangeetha	35/M	House wife	3 months	5-7-2017	26-7-2017	Good Improvement
02	5403	Chinnamma	38/F	House wife	5 months	19-7-2017	9-8-2017	Good Improvement
03	8618	Sasikumar	37/M	Tailor	6 months	14-8-2017	4-9-2017	Good Improvement
04	5412	Mohamed rafik	50\M	Carpenter	4 months	28-8-2017	18-9-2017	Good Improvement
05	7648	Devi bharathi	28\F	House wife	3 months	6-9-2017	27-9-2017	Good Improvement
06	2314	Kaviarsi	29\F	Teacher	2 months	21-9-2017	12-10-2017	Good Improvement
07	8754	Kalpana	32\F	House wife	4 months	9-10-2017	30-10-2017	Good Improvement
08	5719	Selvakumar	42/M	Tailor	1 year	18-10-2017	8-10-2017	Moderate Improvement
09	4532	Gunaseelan	58/M	Coolie	8 months	13-11-2017	4-12-2017	Good Improvement
10	7563	Sekar	59/M	Coolie	2 months	29-11-2017	20-12-2017	Good Improvement
11	8327	Gayathri	27/F	IT sector	1 month	24-12-2017	14-1-2018	Good Improvement
12	589	Vignesh	36/M	Tailor	3 months	3-1-2018	24-1-2018	Good Improvement
13	2687	Sangeetha	48/M	House wife	5 months	21-1-2018	11-2-2018	Good Improvement
14	5608	Arumugam	52/M	Salesman	4 months	27-2-2018	20-3-2018	Good Improvement
15	8436	Janakiraman	45M	Tailor	5 months	5-3-2018	26-3-2018	Good Improvement
16	5389	Sarala	39/F	House wife	6 months	27-3-2018	17-4-2018	Good Improvement
17	3468	Mahalakshmi	49/F	House wife	3 months	29-3-2018	19-4-2018	Good Improvement
18	4187	Mumataj	50/F	House wife	5 months	2-4-2018	23-4-2018	Good Improvement
19	6913	Rajidevi	58/F	House wife	6 months	4-4-2018	25-4-2018	Good Improvement
20	8938	Sivaraman	59/M	Driver	7 months	8-4-2018	29-4-2018	Good Improvement

Laboratory Investigations of OPD patients – Group 1

S.No	OP No	Name	Age/Sex	BT				AT				ESR (mm)				Hb		URINE ANALYSIS						RFT			
				TC	DC			TC	DC			BT		AT		BT	AT	BT			AT			BT		AT	
					P	L	E		P	L	E	½ hr	1 hr	½ hr	1 hr			Alb	Sug	Dep	Alb	Sug	Dep	Urea	Cre	Urea	Cre
1	7785	Pavithra	20/F	6500	53	40	07	8200	68	76	06	07	18	07	16	11.2	11.3	Nil	Nil	Nil	Nil	Nil	Nil	21	0.8	21	0.8
2	7833	Roslin devi	38/F	6800	59	32	09	7400	64	32	04	06	10	06	10	10.0	10.2	Nil	+	Nil	Nil	Nil	Nil	27	1.4	25	1.2
3	8088	Gangammal	54/F	8800	67	26	07	9800	70	27	03	20	39	18	34	9.2	9.5	Nil	++	Opc	Nil	+	Nil	28	1.6	27	1.4
4	8629	Vijay selvam	55/M	9000	70	24	06	9500	68	26	06	06	18	06	18	12.6	12.8	Nil	+	Fpc	Nil	+	Nil	32	1.4	32	1.4
5	9045	Sathyadevi	29/F	8300	61	32	07	9700	68	24	08	08	12	07	12	13.2	13.2	Nil	Nil	Nil	Nil	Nil	nil	25	1.0	22	0.8
6	9745	Mohan	50/M	4600	51	43	07	6600	65	30	05	08	20	07	18	11.4	11.6	Nil	+	Opc	Nil	+	Nil	28	1.2	25	1.0
7	405	Balaji	45/M	7200	64	27	09	9100	72	25	03	15	32	13	29	8.5	9.2	Nil	+	Fpc	Nil	+	Nil	30	0.8	28	0.8
8	2029	Krishna Moorthy	44/M	4700	75	19	06	6400	72	25	03	22	32	15	30	11.6	11.8	Nil	Nil	Nil	Nil	Nil	Nil	25	0.6	22	0.6
9	1595	Tamilselvi	39/F	7500	50	41	09	8600	64	30	06	12	22	10	20	12.5	12.6	Nil	Nil	Opc	Nil	Nil	Nil	28	1.0	25	0.8
10	8509	Sheek	40/M	6400	51	44	05	8800	66	28	06	04	10	04	08	14.2	14.2	Nil	+	Nil	Nil	Nil	Nil	26	0.6	25	0.6
11	446	Bhanumathi	52/F	8800	63	31	06	9100	61	34	05	05	12	05	10	13.2	13.2	Nil	+	Nil	Nil	Nil	Nil	30	1.2	28	1.0
12	2266	Jayaraman	52/M	8900	64	30	06	9000	65	30	05	12	20	11	18	10.2	10.3	Nil	++	Nil	Nil	+	Nil	25	0.6	22	0.6
13	9728	Uma	49/F	7800	64	30	06	8300	53	40	07	08	18	08	18	12	12	Nil	Nil	Opc	Nil	Nil	Nil	32	1.0	28	0.8
14	73	Nagamma	37/F	8900	62	34	04	9500	60	36	04	12	20	10	15	10.5	10.6	Nil	Nil	Nil	Nil	Nil	Nil	28	0.6	26	0.6
15	932	Devi	35/F	4700	69	23	08	6200	70	26	04	20	40	15	25	9	10	Nil	Nil	Nil	Nil	Nil	Nil	18	0.6	18	0.6
16	649	Nanda kumar	51/M	8900	59	36	05	9600	62	35	03	25	55	15	30	8.9	10.5	Nil	+	Nil	Nil	Nil	Nil	23	0.5	21	0.5
17	2671	Meera	60/F	8900	59	35	06	9700	62	36	02	35	65	30	45	11	12	Nil	+	Nil	Nil	+	Nil	20	0.4	18	0.4
18	7987	Vijayakumar	26/M	10000	55	38	07	10500	60	39	01	40	70	15	30	7.7	8.2	Nil	Nil	Opc	Nil	Nil	Nil	27	0.5	24	0.5
19	771	Gunaseelan	29/M	8400	65	32	03	9800	65	31	04	20	50	15	25	10.4	12.8	Nil	Nil	Nil	Nil	Nil	Nil	26	0.6	23	0.6
20	3632	Kalaimani	49/F	8800	56	38	06	9700	58	35	07	40	90	35	60	8.8	104	Nil	++	Opc	Nil	Nil	Nil	19	0.6	18	0.6

Laboratory investigations of OPD patients- Group 2

S.No	OP No	Name	Age/Sex	BT				AT				ESR (mm)				Hb		URINE ANALYSIS						RFT			
				TC	DC			TC	DC			BT		AT		BT	AT	BT			AT			BT		AT	
					P	L	E		P	L	E	½ hr	1 hr	½ hr	1 hr			Alb	Sug	Dep	Alb	Sug	Dep	Urea	Cre	Urea	Cre
1	1075	Usha	30/F	7000	54	38	8	8700	60	38	2	50	90	35	70	9	12	Nil	Nil	Opc	Nil	Nil	Nil	19	0.6	18	0.6
2	7901	Ramalingam	56/M	7800	60	34	6	9000	68	29	3	50	120	25	45	10	11	Nil	+	Nil	Nil	Nil	Nil	28	0.6	26	0.6
3	480	Sindu	26/F	7200	80	11	09	7800	65	33	02	42	90	20	40	09	9.6	Nil	Nil	Fpc	Nil	Nil	Nil	20	0.8	18	0.3
4.	4902	Anuradha	38/F	9500	64	32	04	9800	66	34	0	40	90	35	50	9.6	10.7	Nil	Nil	Opc	Nil	Nil	Nil	20	0.8	18	0.8
5.	5574	Kalaiarasi	30/F	4960	69	23	08	6000	66	30	04	60	100	25	40	8.1	10	Nil	Nil	Opc	Nil	Nil	Nil	18	0.9	18	1.0
6.	9728	Perumal	49/M	7700	54	38	08	9500	60	36	04	30	75	10	25	10.2	11	Nil	Nil	Opc	Nil	Nil	Nil	20	1.2	18	1.2
7.	2630	Ragasudha	42/F	8200	67	29	04	9400	68	28	04	34	72	20	30	9.4	11.5	Nil	+	Nil	Nil	Nil	Nil	29	0.8	25	0.8
8.	9998	Govindarajan	58/M	8500	75	22	03	10400	70	27	03	45	80	15	35	10.3	10.4	Nil	+	Nil	Nil	Nil	Nil	28	0.6	25	0.6
9.	4997	Eshwar	34/M	10400	58	34	08	10200	62	34	04	30	75	10	25	8.4	9.3	Nil	+	Opc	Nil	Nil	Opc	25	0.7	20	0.7
10.	539	Meenakshi	39/F	8600	55	39	06	9700	59	38	03	25	80	20	40	9.7	10.4	Nil	Nil	Nil	Nil	Nil	Nil	36	0.9	32	0.6
11.	9986	Samudhrakani	46/M	6800	68	28	04	8500	60	38	02	20	50	15	35	8.7	9.6	Nil	Nil	Opc	Nil	Nil	Opc	25	0.8	22	0.9
12.	5322	Lakshmi	58/F	7200	62	30	08	9000	69	29	02	26	52	15	25	10.4	11.7	Nil	++	Nil	Nil	+	Nil	22	0.6	20	0.8
13.	481	Rani	40/F	5450	49	45	06	6600	62	35	03	45	80	25	35	8.7	10	Nil	+	Nil	Nil	Nil	Nil	24	0.8	22	0.8
14.	9384	Duraisamy	51/M	10340	72	24	04	11000	70	27	03	30	60	15	30	9.7	9.9	Nil	++	Opc	Nil	+	Opc	26	1.0	24	1.2
15.	2841	Menaka	47/F	8800	59	36	05	10500	64	33	03	40	90	25	30	09	13	Nil	+	Nil	Nil	nil	Nil	29	1.0	25	1.2
16.	2861	Parthasarathy	27/M	7700	50	42	08	8800	55	43	02	55	100	15	20	9.6	10.6	Nil	Nil	Nil	Nil	Nil	Nil	27	1.0	23	1.2
17.	3360	Baghyalakshmi	32/F	8600	60	29	11	9700	60	39	01	34	70	15	40	9.8	12.6	Nil	Nil	Nil	Nil	Nil	Nil	24	0.8	22	1.2
18.	3445	Thirunavukarasu	36/M	4600	60	35	05	7800	66	31	03	34	80	25	55	9.5	9.9	Nil	Nil	Fpc	Nil	Nil	Nil	22	0.6	18	0.6
19.	1234	Manigandan	25/M	9800	65	28	07	10300	69	29	02	60	98	10	15	11	11.5	Nil	Nil	Nil	Nil	Nil	Nil	22	0.6	18	0.8
20.	158	Kalaivani	32/F	6850	54	40	06	9000	58	38	04	40	80	30	50	11.5	12	Nil	Nil	Opc	Nil	Nil	Nil	26	0.8	24	0.8

Laboratory Investigations of OPD Patients- Group 3

S.No	OP No	Name	Age/Sex	BT				AT				ESR (mm)				Hb		URINE ANALYSIS						RFT			
					DC				DC			BT		AT				BT			AT			BT		AT	
				TC	P	L	E	TC	P	L	E	½ hr	1 hr	½ hr	1 hr	BT	AT	Alb	Sug	Dep	Alb	Sug	Dep	Urea	Cre	Urea	Cre
01	2563	Sangeetha	35/M	8100	55	40	05	9000	58	37	05	10	20	08	16	12.1	12.5	Nil	Nil	Nil	Nil	Nil	Nil	26	0.8	25	0.6
02	5403	Chinnamma	38/F	6400	56	38	06	7200	64	30	06	12	25	10	20	12.5	13.1	Nil	Nil	Opc	Nil	Nil	Nil	30	1.0	28	0.8
03	8618	Sasikumar	37/M	7200	62	33	05	7800	60	35	05	40	80	20	40	10.2	10.3	Nil	Nil	Fpc	Nil	Nil	Fpc	18	0.7	18	1.0
04	5412	Mohamed rafik	50\M	8800	70	27	03	9100	72	25	03	15	35	18	36	12.3	12.8	Nil	+	Opc	Nil	+	Nil	24	0.6	26	0.8
05	7648	Devi bharathi	28\F	9200	65	29	06	9000	68	28	04	10	22	12	24	10.0	11.1	Nil	Nil	Nil	Nil	Nil	Nil	30	0.7	28	0.6
06	2314	Kaviarsi	29\F	10500	68	28	04	10800	65	29	06	18	36	16	34	12.2	12.6	Nil	Nil	Nil	Nil	Nil	Nil	24	1.0	26	0.8
07	8754	Kalpana	32\F	8500	72	24	04	8800	70	26	04	15	30	20	40	11.0	11.8	Nil	Nil	Opc	Nil	Nil	Nil	32	0.8	30	0.8
08	5719	Selvakumar	42/M	9500	62	32	06	9200	66	30	04	12	25	18	36	10.0	10.4	Nil	Nil	Opc	Nil	Nil	Nil	20	1.1	22	1.0
09	4532	Gunaseelan	58/M	7200	66	28	06	7400	72	24	04	10	20	12	24	11.0	12.0	Nil	+	Fpc	Nil	+	Nil	28	1.4	26	1.2
10	7563	Sekar	59/M	11000	65	30	05	10800	68	28	04	12	25	20	40	9.6	10.4	Nil	++	Opc	Nil	+	Nil	34	1.6	28	1.4
11	8327	Gayathri	27/F	9700	72	24	04	10000	70	26	04	15	30	22	46	11.4	12.0	Nil	Nil	Nil	Nil	Nil	Nil	30	0.6	28	0.6
12	589	Vignesh	36/M	8400	64	30	06	8600	72	24	04	20	40	18	34	14.0	14.2	Nil	Nil	Nil	Nil	Nil	Nil	35	0.6	34	0.8
13	2687	Sangeetha	48/M	7100	62	32	06	7400	64	34	02	12	26	14	30	12.0	12.2	Nil	+	Nil	Nil	Nil	Nil	24	0.8	26	1.0
14	5608	Arumugam	52/M	9300	68	26	06	9200	70	24	06	08	16	12	24	10.2	10.6	Nil	Nil	Nil	Nil	Nil	Nil	32	1.2	34	1.2
15	8436	Janakiraman	45M	6600	62	36	02	7500	64	32	04	12	26	20	42	12.2	12.5	Nil	+	Nil	Nil	Nil	Nil	28	1.2	32	1.2
16	5389	Sarala	39/F	8600	72	24	04	8800	68	26	06	18	36	22	40	10.5	10.8	Nil	Nil	Opc	Nil	Nil	Nil	34	0.6	30	0.7
17	3468	Mahalakshmi	49/F	9400	59	38	03	9600	62	36	02	20	40	18	36	11	11.2	Nil	Nil	Fpc	Nil	Nil	Nil	32	0.8	30	0.6
18	4187	Mumataj	50/F	10200	68	26	06	10700	70	24	06	12	26	14	28	10	10.3	Nil	+	Opc	Nil	Nil	Nil	28	1.4	32	1.2
19	6913	Rajidevi	58/F	8800	66	32	02	8900	68	30	02	15	30	18	34	9.4	10.2	Nil	+	Nil	Nil	Nil	Nil	34	0.8	29	0.7
20	8938	Sivaraman	59/M	9300	70	24	06	9500	72	26	02	18	34	22	40	10.2	10.8	Nil	+	Opc	Nil	Nil	Nil	32	1.2	34	1.2

DISCUSSION

The present study was conducted to evaluate the safety and therapeutic efficacy of "Kurunthotti kashayam"(Internal medicine) and "Azhinjil Thailam" (External medicine) and to compare along with the effect of Varmam therapy, in Sagana vatham at OPD of PG Department of Varmam, Puramaruthuvam and Sirappu maruthuvam, Aringnar Anna Government Hospital of Indian medicine and Homoeopathy.

Sagana vatham is characterized by

S.No	Saganavatham as per literature	Translation
1	கேழுமே கழுத்திங்கீ ழரைக்கு மேலுங் கெடியான கரமிரண்டு மிகவே நொந்து	Pain Extending from neck to hip and both upper limbs
2	வாளுமே சரீரமெல்லாம் கனத்திருக்கும்	A sort of heavy feel in the body.
3	வாலிபர்க்கு மனங்கண்ணு மயக்கமாகும்	Mental symptoms and failing eye sight in the Young adults.
4	ஏளுமே யிரண்டுகண்ணு மயக்கமாகும்	Burning sensation in the eyes
5	மேற்றமாய் சலந்தானு மிறுகிக்கானுந்	Presenting of Urinary symptoms like concentrated urine probably because of bladder disturbances
6	தேளுமே கொட்டினது போற்க டுக்கும்	Sharp and Stinging (lancinating) pain with agony

Cervical spondylosis is defined as arthorosis of the posterior intervertebral joints in the cervical vertebrae. It is common in the middle aged and in the elderly particularly in those whose occupation involves a posture of prolonged neck flexion. (1) .This is characterised by pain in nape of the neck (local /referred pain),radiating pain in upper limbs, tenderness, Numbness, Stiffness of neck, Restriction of movements of neck, Giddiness, Sensory loss & paraesthesia in the corresponding dermatomes (due to sensory root involvement), Weakness of muscles supplied (due to motor root involvement).

In the present study 60 patients between the age group of 20-60 years as per inclusion criteria as mentioned above were categorized into three groups. The study period was between Jun 2017 to Jun 2018. The groups were designated as G1, G2 and G3; G1 was subjected to Kurunthotti Kashayam alone, G2 was subjected to Kurunthotti Kashayam (Int), & Azhinjil Thylam (Ext), and G3 was subjected to both Internal and External medicine, and along with Varmam manipulation therapy.

Observation period was fixed at 21 days.

AGE DISTRIBUTION

Among 60 cases, 18.3% of cases were in the age group of 20-30, 28.3 %, 23.3%, and 30% of cases were in the age of 31-40, 41-50 and 51-60 respectively.

GENDER DISTRIBUTION

Among 60 cases, 48.3% of cases were Males and 48.3% of patients were females.

OCCUPATIONAL DISTRIBUTION

Among 60 cases, 33% of cases were House wives, 30% of cases were Tailors, 12% were Drivers, 10% of cases were IT employees. Coolie, Salesmen and Teachers were 8% each. Carpenters and Electricians were 3% each.

SOCIO ECONOMIC STATUS:

Among 60 patients, 36.6%, 33.3% and 30% of cases belong to Low, middle and High income category respectively.

DIET:

Among 60 cases, 86.6% of cases were consuming mixed diet and 13.3% were Vegetarian

DURATION OF ILLNESS:

Out of 60 patients subjected in the present study, 11.6% belonged to less than 1 month of illness and others were 26.6% in 1-3 months, 30% in 4-6 months, 20% in 6 month – 1year and 11.6% in 1 year of illness.

DISTRIBUTION AMONG PARUVAKAALAM:

Among 60 patients, 46.6%, 5%, 5%, 11.6% and 31.6% of patients came in Kaar, koothir, Munipani, Pinpani and Muthuvenil kaalam. No cases were came in Ilavenil kaalam.

THINAI DISTRIBUTION:

Out of 60 patients, 91.6% of patients belongs to Neithal Nilam and 8.3% of patietns belong to Marutha Nilam

KAALAM DISTRIBUTION:

Out of 60 patients, 30% of patients were belonged Vatha kaalam and 60% belonged to Pitha kaalam.

DISTRIBUTION OF VATHAM:

Out of 60 Patients, Udanan and Samanan were affected in all the patients. Pranan and abanan were affected in 48% and 16% of patients respectively.

DISTRIBUTION OF PITHAM:

Out of 60 patients, Anarpitham was affected in 65% of patients and Saathaga pitham was affected in all the patients (100%).

DISTRIBUTION OF KABAM:

Out of 60 patients, Santhigam was affected in all patients (100%) and Kilethagam was affected in 65% of patients.

DISTRIBUTION OF ENVAGAI THERVU:

Out of 60 patients, Nadi was affected in100% of patients, Sparism was affected in 60% of patients and Malam was affected in48% of patients.

DISTRIBUTION OF NEIKKURI:

Out of 60 patient's urine sample vatha neer was present in 60% of patient's urine sample, Pitha neer was present in 30% of patient's urine sample and Kaba neer was present in 10% of urine sample.

DISTRIBUTION OF NADI:

Out of 60 patients, Vatha pitha nadi, Pitha vatha nadi and vatha nadi were present in 53%, 30% and 17% of patients.

Treatment outcome:

The comparative study of *Kurnthotti kashayam* alone, Kurnthotti kashayam with azhinjil thailam (ext) and combined therapy of both with *Varmam* was done in three groups each comprising 20 patients. The patient's response to *kurunthotti kashayam* alone (G1), *kurunthotti kashayam with Azhinjil thailam* (G2) and in combined therapy of *Kurunhtotti kashayam*, *Azhinjil thailam* and *Varmam* (G3) was tried on 60 patients in three groups of 20 each the following inferences were made on the basis of **Visual analog scale.**

In Group I, 65% of patients had Good improvement, 15% of patients had moderate and mild improvement each and 5% of patients had No improvement.

In Group II, 85% of patients had Good improvement, 10% of patients had moderate improvement and 5% of the patients showed Mild improvement.

In Group III, 95% of patients had Good improvement, 5% of patients had moderate improvement.

The patient's response in G1, G2 and G3 of 20 each on the basis of **Clinical parameters** are as follows:

66% of Patients responded in Group I

90% of Patients responded in Group II

96% of Patients responded in Group III

The result of subjective parameters had revealed that Group 2 and Group 3 have shown significant improvement than Group I in reducing all symptoms of *Saganavatham* which is 90% and 96% respectively.

Thus, on comparing the three Groups, Group 3 which was given the combined therapy of Kurunthotti kashayam (Int), Azhinjil Thailam (Ext) and Varmam had shown significant improvement with symptomatic management in Saganavatham.

SUMMARY

The aim of the study is to compare and evaluate the safety and efficacy of Kurunthotti Kashayam (Int) and Azhinjil Thylam (Ext), and Varmam therapy intervention for saganavatham.

The study consisted of four parts namely,

1. Analytical testing as per AYUSH protocol.

2. Toxicity studies – Acute and Sub-acute toxicity studies as per OECD guidelines.(423&407).

3. Pharmacological studies- Anti inflammatory and analgesic activity

4. Clinical trial into three groups

The analytical testing as per AYUSH protocol for evaluating *Kurunthotti Kashayam chooranam* was done at Indian Institute of Technology exemplified that the polyherbal formulation Kurunthotti Kashayam has no heavy metals as per ICPO-ES, and FT-IR analysis for functional group present in the drug.

Phytochemical screening revealed the presence of Flavanoids, proteins, amino acids, alkaloids, tannins, hydroquinone derivatives in methanolic and acetone extract. Terpenes were estimated in chloroform extract.

The drug namely Kurunthotti Kashayam was prepared and tested for toxicity studies, pharmacological studies at C L Baid Metha College of pharmacy. Acute and repeat dose oral toxicity study of Kurunthotti Kashayam revealed that the drug was safe. Histopathological studies have shown that the drug has no toxic effects in the vital organs.

Analgesic activity of Kurunthotti Kashayam in wistar albino rats in acetic acid induced writhing test indicated that kurunthotti kashayam had shown dose dependent activity against standard diclofenac sodium .

In vivo anti inflammatory activity of the test drug in wistar albino rats using carageenan induced paw edema method revealed that the drug has anti inflammatory activity with reference drug indomethacin.

The study was approved by the Institutional Ethical Committee (IEC). The clinical trial is also registered in Clinical Trial Registry of India (CTRI).

The comparative study of Kurunthotti kashayan alone (Group1), Kurunthotti kashayam and azinjil thylam (Group 2) and Kurunthotti kashayam, Azhinjil thailam with Varmam therapy (Group 3) was done in three groups each comprising 20 patients. The inferences were made. All three groups shown statistically significant improvement.

Primary outcome was assessed by Visual Analog Scale (Universal Pain Assessment Scale). Secondary outcome i.e reduction in clinical parameters was also assessed.

Among the three groups Group 3 shown better improvement than the other two groups.

Statistical analysis was performed to assess the significance of the clinical trial.

CONCLUSION

Kurunthotti Kashayam (KK) a Polyherbal preparation was chosen for studying its efficacy on Saganavatham as internal medicine.

Heavy metal analysis of KK reveal that the drug does not contain any metals like lead,cadmium,arsenic,mercury.

Phyto chemical study shown that the trial drug KK has Alkaloids, coumarins, saponins, tanins, glycosides, flavonoids, phenols, steroids, Triterpenoids, anthocyanin, carbohydrates and proteins.

The acute & Subacute toxicity study reveals that the trial drugs KK is safe, Sub acute toxicity study two doses were administrated orally for 28 days. Animals were observed for physiological and behavioural changes food and water, intake body, weight, mortality. All the animals were sacrificed, the changes in organ weight and histology were examined no mortality were observed and no treatment related changes seen. Hence the siddha trial drugs KK is safe in animal models.

Pharmacological study shown that the drug Kurunthotti Kashayam has significant Anti inflammatory and Analgesic activity.

In Group I, 65% of patients had Good improvement, 15% of patients had moderate and mild improvement each and 5% of patients had No improvement.

In Group II, 85% of patients had Good improvement, 10% of patients had moderate improvement and 5% of the patients showed Mild improvement.

In Group III, 95% of patients had Good improvement, 5% of patients had moderate improvement.

Group III had shown better results over the other two groups.

During the course of treatment there were no adverse effects or unwanted drug reactions in GIT,CVS, RS & Excretory systems.

Hence it is concluded that the combined therapy of Kurunthotti Kashayam (internal), Azhinjil thailam and Varmam gives significant improvement in the treatment of Saganavatham (Cervical Spondylosis)

GOVERNMENT SIDDHA MEDICAL COLLEGE

Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-5/014/2016

Protocol title:

AN OPEN COMPARATIVE CLINICAL EVALUATION ON SAGANAVATHAM (CERVICAL SPONDYLOSIS) WITH SIDDHA HERBAL FORMULATION DRUG "KURUNTHOTTI KASHAYAM" (INT), "AZHINJIL THYLAM" (EXT) AND "VARMAM"

Principal Investigator: Dr. R. RASAKUMAR

Name & Address of Institution:

Government Siddha Medical College,

Arumbakkam, Chennai-106

☑ New Review ☐ Revised Review ☐ Expedited Review

Date of review (DD/MM/YY): 05-04-2016

Date of Previous Review, If Revised Application:

Decision of the IEC

☑ Recommended ☐ Recommended with suggestions

☐ Revision ☐ Rejected

Suggestions / Reasons / Remarks: 1) Add cervical rib in exclusion criteria.
2) Change Kashayam dosage as 60ml.
3) A simple Randomization will be done for trail groups.

Recommended for a period of 1 year
from date of completion of preclinical studies :

Please Note:

- Inform IEC immediately in case of any adverse events/serious drug reaction.
- Seek IECapproval in case of any change in the study procedure, site and investigator
- This approval is valid only for period mentioned above
- IEC member have the right to review the trial with prior intimation.

5/4/16

Dr.P.Jeyaprakashnarayanan, M.D(s)
Chairman

Dr.K.Kanakavalli, M.D(s)
Member Secretary

INSTITUTIONAL ETHICS COMMITTEE

Date : 05.04.2016
Sub : IEC review of research proposals.
Ref : Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
Dr.P.JEYAPRAKASH NARAYANAN, M.D(S)., Chairman	✓	
Dr.K.KANAKAVALLI, M.D(S)., Member secretary	✓	
Dr.P.SATHYA RAJESWARAN, M.D(S)., Clinician – Siddha	✓	
Dr.N.KABILAN, M.D(S)., Clinician – Siddha	✓	
Dr.R.VASUDEVAN, M.D(S)., PG.DIP (Clinical research), Msc (Medical sociology) Sociologist	✓	
Dr.L.MUKUNTHAN, M.B.B.S., DNB (Medicine)., Modern Medicine Specialist	✓	
Dr. JOSEPH MARIYA ADAIKKALAM,M.D(S)., Msc epidemiology., Social scientist	✓	
Dr.G.AADINATH REDDY, M.Pharm, Ph,D., Biomedical scientist	✓	
Mr.B.PADMANABHA PILLAI Philosopher	✓	
Mrs. PREETHA SARAVANAN Public person	✓	

Dr. P. Jeyaprakashnarayanan, M.D(s)
Chairman

Dr.K. Kanakavalli, M.D(s)
Member secretary

C.L.BAID METHA COLLEGE OF PHARMACY

(An ISO 9001-2000 certified institute)

Jyothi Nagar, Old Mahabalipuram Road

Thoraipakkam, Chennai – 600 097

CERTIFICATE

This is to certify that the project entitled, Toxicological and Pharmacological study on **KURUNTHOTTI KASHAYAM** in rats submitted in partial fulfilment for the degree of M.D. (siddha) was carried out at C.L. Baid Metha college of Pharmacy, Chennai-97, in the Department of Pharmacology during the academic year of 2016-2017. It has been approved by the IAEC No: XLVIII/26/CLBMCP/2016

C.L. Baid Metha College of Pharmacy CHENNAI-97 Thoraipakkam

Dr.P.MURALIDHARAN

Physicochemical Evaluation

Project ID	**NRS/AS/0081/01/2018**
Name and Address of the Researcher	**Dr.Rasakumar** **Department of Special Medicine** **Govt Siddha Medical College, Chennai** **Tamilnadu, India**
Parameter Requested by the Customer for Analysis	**Physicochemical Analysis**
Sample Received	**Post**
Sample –ID	**KK**

Final Test report

S.No	Parameter	Mean (n=3) SD
1.	***Loss on Drying at 105 °C (%)***	14.23 ± 1.68
2.	***Total Ash (%)***	10.17 ± 0.26
3.	***Acid insoluble Ash (%)***	11.73 ± 1.22
4.	***Water Soluble Ash (%)***	15.07 ± 1.72
5.	***Alcohol Soluble Extractive (%)***	23.9 ± 1.14
6.	***Water soluble Extractive (%)***	19.57 ± 1.75
7.	***PH***	5.1

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We Trust in Quality and Ethics

E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 - 42691289

Project ID	NRS/AS/0081/01/2018
Name and Address of the Researcher	Dr.Rasakumar Department of Special Medicine Govt Siddha Medical College, Chennai Tamilnadu, India
Parameter Requested by the Customer for Analysis	Physicochemical Analysis
Sample Received	Post
Sample –ID	KK
Description of the Sample	Solid
Method of Analysis	PLIM- Protocol – ASU Formulations
Analysis Type	Physicochemical Analysis
Date of Analysis	02/03/2018
Result of Analysis	Test and Analytical Reports Attached As Annexures

Test Report

S.NO	TEST	OBSERVATION
1	ALKALOIDS	-
2	FLAVANOIDS	+
3	GLYCOSIDES	-
4	STEROIDS	+
5	TRITERPENOIDS	+
6	COUMARIN	+
7	PHENOL	+
8	TANIN	+
9	PROTEIN	-
10	SAPONINS	+
11	SUGAR	+
12	ANTHOCYANIN	-
13	BETACYANIN	+

Note: +-> Indicates Presence and - -> Indicates Absence of the Phytocomponents

SOPHISTICATED ANALYTICAL INSTRUMENT FACILITY

IITM, CHENNAI-36

PERKIN ELMER OPTIMA 5300 DV ICP-OES

Elements Symbol Wavelength (nm)	**Concentration**
K.K----------	
(wt:0.41300g)	
Al 396.152	BDL
As 188.979	BDL
Ca 315.807	142.150 mg/L
Cd 228.802	BDL
Cu 327.393	BDL
Fe 238.204	01.016 mg/L
Hg 253.652	BDL
K 766.491	53.004 mg/L
Mg 285.213	01.004 mg/L
Na 589.592	21.100 mg/L
Ni 231.604	BDL
Pb 220.353	BDL
P 213.617	306.351 mg/L
S 180.731	01.314 mg/L
Zn 206.200	01.018 mg/L

Government Siddha Medical College
Department of Medicinal Botany

Dr. S. Sankaranarayanan M.Sc., M.Phil., Ph.D.,
Asst. Professor
Head of the Department

6, Anna Arch Rd,
NSK Nagar,
Arumbakkam, Chennai,
Tamil Nadu 600106.

AUTHENTICATION CERTIFICATE

Based upon the organoleptic/macroscopic/microscopic examination of fresh/market sample, it is certified that the specimen given to Dr. R. RasaKumar B.S.M.S, doing M.D. (S) at Government Siddha Medical College, Arumbakkam, Chennai-106 is identified below as

Binomial name	Family	Voucher Specimen No
Sida rhombifolia	Malvaceae	GSMC/MB-55/17
Allium sativum	Liliaceae	GSMC/MB-56/17
Ricinus communis	Euphorbiaceae	GSMC/MB-57/17
Vitex negundo	Verbenaceae	GSMC/MB-58/17
Echolium linneanum	Convolvulaceae	GSMC/MB-59/17
Cedrus deodara	Pinnaceae	GSMC/MB-60/17
Alpinia offinarum	Zingiberaceae	GSMC/MB-61/17
Alpinia galanga	Zingiberaceae	GSMC/MB-62/17

References: Flora of Presidency, Gamble, J. S

Date: 01.06.2017

01/06/17

Dr. S. Sankaranarayanan M.Sc., M.Phil., Ph.D.,
Head
Dept. of Maruthuva Thavaraiyal
(Medicinal Botany and Pharmacognosy)

Clinical Trial Details (PDF Generation Date :- Wed, 27 Jun 2018 16:41:07 GMT)

CTRI Number	CTRI/2018/02/011686 [Registered on: 05/02/2018] - **Trial Registered Retrospectively**
Last Modified On	30/01/2018
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Drug Siddha
Study Design	Single Arm Trial
Public Title of Study	A study on siddha trail drug Kurunthotti Kashayam (Int) Azhinjil Thylam (Ext) and Varmam in patients having neck pain
Scientific Title of Study	An open comparative clinical evaluation on Saganavatham (Cervical spondylosis) with siddha herbal formulation drug Kurunthotti Kashayam (Int) Azhinjil Thylam (Ext) and Varmam

Secondary IDs if Any

Secondary ID	Identifier
Nil	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr R Rasakumar
Designation	PG scholar
Affiliation	Government Siddha Medical College
Address	Post Graduate Department of Sirappu Maruthuvam Government Siddha Medical College No 6 Anna arch road NSK Nagar Arumbakkam Chennai Chennai TAMIL NADU 600106 India
Phone	9843172369
Fax	
Email	rasakumar29@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr M Mohamed Musthafa
Designation	Reader
Affiliation	Government Siddha Medical College
Address	Post Graduate Department of Sirappu Maruthuvam Government Siddha Medical College No 6 Anna arch road NSK Nagar Arumbakkam Chennai Chennai TAMIL NADU 600106 India
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Fax	
Email	spmhibiscus@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr R Rasakumar
Designation	PG Scholar
Affiliation	Government Siddha Medical College
Address	Post Graduate Department of Sirappu Maruthuvam Government Siddha Medical College No 6 Anna arch road NSK Nagar Arumbakkam Chennai Chennai

	TAMIL NADU 600106 India
Phone	9843172369
Fax	
Email	rasakumar29@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Government Siddha Medical College No 6 Anna Arch road NSK Nagar Arumbakkam Chennai 106

Primary Sponsor

Primary Sponsor Details	
Name	Government Siddha Medical College
Address	No 6 Anna Arch road NSK Nagar Arumbakkam Chennai 106
Type of Sponsor	Government medical college

Details of Secondary Sponsor

Name	Address
Nil	Nil

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr R Rasakumar	Arignar Anna Hospital of Indian Medicine	Room No 4 Siddha Division Post Graduate Department of Sirappu Maruthuvam Arignar Anna Hospital of Indian Medicine Anna arch road NSK Nagar Arumbakkam Chennai 106 Chennai TAMIL NADU	9843172369 rasakumar29@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional ethics committee	Approved	05/04/2016	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Saganavatham (Cervical spondylosis)

Intervention / Comparator Agent

Type	Name	Details
Intervention	Kurunthotti kashayam (Internal) and Azhinjil Thylam (EXternal)	60 ml of kurunthotti kashayam for 48 days as internal medcine and Azhinjil thylam for 48 days as external medicine
Comparator Agent	Nil	Nil

Inclusion Criteria

Inclusion Criteria	
Age From	20.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	1. Pain in the nape of the neck 2. Radiating pain to the upper limbs up to the tip of the fingers with or

		without numbness in the upper limbs 3. Giddiness 4. Neck stiffness

Exclusion Criteria

Exclusion Criteria	
Details	History of 1.Trauma. 2. Thoracic outlet syndrome. 3. Cervical IVDP. 4. Congenital anomalies of spine like Torticolis, Spina bifida & scoliosis. 5. Sero Negative Spondylarthropathy like Ankylosing spondylitis, Polyarthritis etc… 6. Syringomyelia. 7. Tuberculosis of spine 8. Neuropathic arthropathy in Diabetes mellitus 9. Cardiac diseases 10. Neoplasms 11. Pregnancy & Lactation 12. Patients with any other serious systemic illness

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Case Record Numbers
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
Outcome is reduction of pain in neck which is assessed by Visual analog scale	nil

Secondary Outcome

Outcome	Timepoints
Nil	Nil

Target Sample Size	**Total Sample Size=**60 **Sample Size from India=**60
Phase of Trial	Phase 2
Date of First Enrollment (India)	10/07/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	None yet
Brief Summary	This is an open clinical study to evaluate the efficacy of Kurunthotti Kashayam (Internal) and Azhinjil Thylam (External). 60 mlKurunthotti kashayam and sufficient quantity of Azhinjil Thylam will be given for 48 days. Varmam therapy is given for all the patients.Sample size is 60. The trial drugs Kurunthotti Kashayam and Azhinjil Thylam contain some active herbs having anti inflammatory and analgesic properties which will be helpful to cure Cervical spondylosis

The Tamil Nadu Dr.M.G.R.Medical University

69, Anna Salai, Guindy, Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs.....R. RASA KUMAR.....

For participating as ~~Resource Person~~ / Delegate in the Twentieth Workshop on

"RESEARCH METHODOLOGY & BIOSTATISTICS"

*For **AYUSH Post Graduates & Researchers***

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University From 07th to 11th March 2016.

Dr.N.KABILAN, M.D.(S)
PROF & HEAD
DEPT.OF SIDDHA

Prof.**Dr.P.ARUMUGAM,** M.D.,
REGISTRAR i/c

Prof. **Dr.S.GEETHALAKSHMI,** M.D., Ph.D.,
VICE CHANCELLOR

ACUTE ORAL TOXICITY STUDY OF *KURUNTHOTTI KASHAYAM*

(OECD GUIDELINE – 423)

Introduction:

- The acute toxic class method is a stepwise procedure with the use of 3 animals of a single sex per step.
- Depending on the mortality and/or the moribund status of the animals, on average 2-4 steps may be necessary to allow judgement on the acute toxicity of the test substance.
- This procedure is reproducible, uses very few animals and is able to rank substances in a similar manner to the other acute toxicity testing methods.
- The acute toxic class method is based on biometric evaluations with fixed doses, adequately separated to enable a substance to be ranked for classification purposes and hazard assessment.
- In principle, the method is not intended to allow the calculation of a precise LD50, but does allow for the determination of defined exposure ranges where lethality is expected since death of a proportion of the animals is still the major endpoint of this test.
- The method allows for the determination of an LD50 value only when at least two doses result in mortality higher than 0% and lower than 100%.
- The use of a selection of pre-defined doses, regardless of test substance, with classification explicitly tied to number of animals observed in different states improves the opportunity for laboratory to laboratory reporting consistency and repeatability.

Principle of the Test:

It is the principle of the test that based on a stepwise procedure with the use of a minimum number of animals per step, sufficient information is obtained on the acute toxicity of the test substance to enable its classification. The substance is administered orally to a group of experimental animals at one of the defined doses. The substance is tested using a stepwise procedure, each step using three animals of a single sex. Absence or presence of compound-related mortality of the animals dosed at one step

will determine the next step, i.e.

− no further testing is needed

− dosing of three additional animals, with the same dose

− dosing of three additional animals at the next higher or the next lower dose level. The method will enable a judgment with respect to classifying the test substance to one of a series of toxicity classes.

Methodology:

Selection of Animal Species

The preferred rodent species is the wistar albino rat, although other rodent species may be used. Healthy young adult animals are commonly used laboratory strains should be employed. Females should be nulliparous and non-pregnant. Each animal, at the commencement of its dosing, should be between 6 to 8 weeks old and the weight (150-200gm) should fall in an interval within±20 % of the mean weight of any previously dosed animals.

Housing and Feeding Conditions

The temperature in the experimental animal room should be 22ºC ± 3ºC. Although the relative humidity should be at least 30% and preferably not exceed 70% other than during room cleaning the aim should be 50-60%. Lighting should be artificial, the sequence being 12 hours light, 12 hours dark. For feeding, conventional laboratory diets may be used with an unlimited supply of drinking water. Animals may be group-caged by dose, but the number of animals per cage must not interfere with clear observations of each animal.

Preparation of animals:

The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions

Test Animals and Test Conditions:

Sexually mature Female Wistar albino rats (150-200gm) were obtained from TANUVAS, Madhavaram, Chennai. All the animals were kept under standard

environmental condition (22±3°C). The animals had free access to water and standard pellet diet (Sai meera foods, Bangalore).

Preparation of animals:

The animals are randomly selected, marked to permit individual identification, and kept in their cages for at least 7 days prior to dosing to allow for acclimatization to the laboratory conditions

Preparation for Acute Toxicity Studies

Rats were deprived of food overnight (but not water 16-18 h) prior to administration of the, ***KURUNTHOTTI KASHAYAM***.

The principles of laboratory animal care were followed and the Institutional Animal Ethical Committee approved the use of the animals and the study design

IAEC approved Number: 1248/AC/09/CPCSEA-9/DEC-2013/12

Test Substance : **KURUNTHOTTI KASHAYAM**
Animal Source : TANUVAS,Madhavaram, Chennai.
Animals : Wister Albino Rats (Female-3+3)
Age **:** 6-8 weeks
Body Weight on Day 0 **:** 150-200gm.
Acclimatization **:** Seven days prior to dosing.
Veterinary examination **:** Prior and at the end of the acclimatization period.
Identification of animals **:** By cage number, animal number and individual marking by using Picric acid.
Number of animals : 3 Female/group,
Route of administration : Oral

Diet **:** Pellet feed supplied by Sai meera foods Pvt Ltd, Bangalore
Water **:** Aqua guard portable water in polypropylene bottles.
Housing & Environment **:** The animals were housed in Polypropylene cages provided with bedding of husk.

Housing temperature **:** between 22ºC ± 3ºC.

Relative humidity **:** between 30% and 70%,

Air changes **:** 10 to 15 per hour and

Dark and light cycle **:** 12**:**12 hours.

Duration of the study **:** 14 Days

Administration of Doses:

KURUNTHOTTI KASHAYAM was suspended in water and administered to the groups of wistar albino rats in a single oral dose by gavage using a feeding needle. The control group received an equal volume of the vehicle. Animals were fasted 12 hours prior to dosing. Following the period of fasting, the animals were weighed and then the test substance was administered. Three Female animals are used for each group. The dose level of 5, 50, 300 and 2000 mg/kg body weight was administered stepwise. After the substance has been administered, food was withheld for a further 3-4 hours. The principle of laboratory animal care was followed. Observations were made and recorded systematically and continuously as per the guideline after substance administration. The visual observations included skin changes, mobility, aggressively, sensitivity to sound and pain, as well as respiratory movements. Finally, the number of survivors was noted after 24 hrs and these animals were then monitered for a further 14 days and observations made daily. The toxicological effect was assessed on the basis of mortality.

Observations:

Animals are observed individually after dosing at least once during the first 30 minutes, periodically during the first 24 hours, with special attention given during the first 4 hours, and daily thereafter, for a total of 14 days, except where they need to be removed from the study and humanely killed for animal welfare reasons or are found dead. It should be determined by the toxic reactions, time of onset and length of recovery period, and may thus be extended when considered necessary. The times at which signs of toxicity appear and disappear are important, especially if there is a tendency for toxic signs to be delayed. All observations are systematically recorded with individual records being maintained for each animal.

Observations include changes in skin and fur, eyes and mucous membranes, and also respiratory, circulatory, autonomic and central nervous systems, and somatomotor

activity and behavior pattern. Attention was directed to observations of tremors, convulsions, salivation, diarrhoea, lethargy, sleep and coma. The principles and criteria summarized in the Humane Endpoints Guidance Document taken into consideration. Animals found in a moribund condition and animals showing severe pain or enduring signs of severe distress was humanly killed. When animals are killed for human reasons or found dead, the time of death was recorded.

Acute oral toxicity study of KURUNTHOTTI KASHAYAM

Table 1: Dose finding experiment and its behavioral Signs of acute oral Toxicity

Observation done:

SL	Group CONTROL	Observation	SL	Group TEST GROUP	Observation
1	Body weight	Normal	1	Body weight	Normally increased
2	Assessments of posture	Normal	2	Assessments of posture	Normal
3	Signs of Convulsion Limb paralysis	Normal	3	Signs of Convulsion Limb paralysis	Absence of sign (-)
4	Body tone	Normal	4	Body tone	Normal
5	Lacrimation	Normal	5	Lacrimation	Absence
6	Salivation	Normal	6	Salivation	Absence
7	Change in skin color	No significant color change	7	Change in skin color	No significant color change
8	Piloerection	Normal	8	Piloerection	Normal

9	Defecation	Normal	9	Defecation	Normal
10	Sensitivity response	Normal	10	Sensitivity response	Normal
11	Locomotion	Normal	11	Locomotion	Normal
12	Muscle gripness	Normal	12	Muscle gripness	Normal
13	Rearing	Mild	13	Rearing	Mild
14	Urination	Normal	14	Urination	Normal

Behaviour:

The animals will be observed closely for behaviour in the first four hours which includes abnormal gait, aggressiveness, exophthalmos, ptosis, akinesia, catalepsy, convolusion, excitation, head twitches, lacrimation, loss of corneal reflex, loss of traction, piloerection reactivity of touch, salivation, scratching, sedation, chewing, head movements, sniffing, straub, tremor and writhes, diarrhea, leathery, sleep and coma.

Body Weight:

Individual weight of animals was determined before the test substance was administered and weights will be recorded at day 1, 7, and 14 of the study. Weight changes were calculated and recorded. At the end of the test, surviving animals were weighed and humanly killed.

Food and water Consumption:

Food and water consumed per animal was calculated for control and the treated dose groups.

Mortality:

Animals were observed for mortality throughout the entire period.

Results:

All data were summarized in tabular form, (Table-1-4) showing for each test

group the number of animals used, the number of animals displaying signs of toxicity, the number of animals found dead during the test, description of toxic symptoms, weight changes, food and water intake

No of animals in each group:3

Table 2 (Observational study Results)

No	Dose mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.	Control	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2.	2000mg	+	-	-	+	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-

1..Alertness 2. Aggressiveness 3. Pile erection 4. Grooming 5. Gripping 6. Touch Response 7. Decreased Motor Activity 8. Tremors 9. Convulsions 10. Muscle Spasm 11. Catatonia 12. Muscle relaxant 13. Hypnosis 14. Analgesia 15.Lacrimation 16. Exophthalmos 17. Diarrhea 18. Writhing

19. Respiration 20. Mortality.

(+ Present, - Absent)

Table 3 (Body weight Observation)

DOSE	DAYS		
	1	7	14
CONTROL	320.2±42.30	322.4 ± 60.10	323.6 ±52.10
HIGH DOSE	302.4± 1.21	302 ± 2.04	304.2 ± 2.10
P value (p)*	NS	NS	NS

Table 3 (Water intake (ml/day) of Wistar albino rats group exposed to *KURUNTHOTTI KASHAYAM):*

DOSE	DAYS		
	1	6	14
CONTROL	58 ± 1.02	58±9.20	59.4±1.04
HIGH DOSE	59.4±2.20	59.8±3.40	59.9±6.24
P value (p)*	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One-way ANOVA followed by Dunnett's test)

Table 4: Food intake (gm/day) of Wistar albino rats group exposed to *KURUNTHOTTI KASHAYAM*

DOSE	DAYS		
	1	7	14
CONTROL	61.04±2.62	62.2±4.76	64.3±6.26
High DOSE	69.4±4.23	70.4±6.22	71.6±4.18

REPEATED DOSE 28-DAY ORAL TOXICITY (407) STUDY OF *KURUNTHOTTI KASHAYAM*

Test Substance : **KURUNTHOTTI KASHAYAM**
Animal Source : TANUVAS, Madhavaram, Chennai.
Animals : Wister Albino Rats (Male -24, and Female-24)
Age **:** 6-8 weeks
Body Weight **:** 150-200gm.
Acclimatization **:** Seven days prior to dose.
Veterinary examination **:** Prior and at the end of the acclimatization period.
Identification of animals **:** By cage number, animal number and individual marking by using Picric acid

Diet	**:** Pellet feed supplied by Sai Meera Foods Pvt Ltd, Bangalore
Water	**:** Aqua guard portable water in polypropylene bottles.
Housing & Environment	**:** The animals were housed in Polypropylene cages provided with bedding of husk.
Housing temperature	**:** between 22ºC±3ºC.
Relative humidity	**:** between 30% and 70%,
Air changes	**:** 10 to 15 per hour
Dark and light cycle	**:** 12**:**12 hours.
Duration of the study	**: 28 Days.**

Table 5

Groups	**No of Rats**
Group I Vehicle control (Water)	12(6male,6 female)
Group II PCM- low dose X (9mg)	12 (6male,6 female)
Group III PCM- Mid dose 10X (90mg)	12 (6male,6female)
Group IV PCM- High dose 20X(180mg)	12(6male,6female)

PCM - KURUNTHOTTI KASHAYAM

Methodology

Randomization, Numbering and Grouping of Animals:

48 Wistar Albino Rats (24M + 24F) were selected and divided into 4 groups. Each group consist of 12 animals (Male -6, and Female-6). First group treated as a control and other three group were treated with test drug (low, mid, high) for 28 days. Animals were allowed acclimatization period of 7 days to laboratory conditions prior to the initiation of treatment. Each animal was marked with picric acid. The females were nulliparous and non-pregnant.

Justification for Dose Selection:

As per OECD guideline three dose levels were selected for the study. They are low dose (X), mid dose (10X), high dose (20X). X is calculated by multiplying the therapeutic dose (500 mg) and the body surface area of the rat (0.018). i.e X dose is (9mg/kg), 10X dose is (90mg/kg), 20X dose is (180mg/kg).

Preparation and Administration of Dose:

KURUNTHOTTI KASHAYAM suspended in with water, It was administered to animals at the dose levels of X, 10X, 20X. The test substance suspensions were freshly prepared every two days once for 28 days. The control animals were administered vehicle only. The drug was administered orally by using oral gavage once daily for 28 consecutive days.

Observations:

Experimental animals were kept under observation throughout the course of study for the following:

Body Weight:

Weight of each rat was recorded on day 0, at weekly intervals throughout the course of study.

Food and water Consumption:

Food and water consumed per animal was calculated for control and the treated dose groups.

Clinical signs:

All animals were observed daily for clinical signs. The time of onset, intensity and duration of these symptoms, if any, were recorded.

Mortality:

All animals were observed twice daily for mortality during entire course of study.

Necropsy:

All the animals were sacrificed by excessive anesthesia on day 29. Necropsy of all animals was carried out.

Laboratory Investigations:

Following laboratory investigations were carried out on day 29 in animals fasted over-night. Blood samples were collected from orbital sinus using sodium heparin (200IU/ml) for Bio chemistry and potassium EDTA (1.5 mg/ml) for Hematology as anticoagulant. Blood samples were centrifuged at 3000 r.p.m. for 10 minutes.

Haematological Investigations:

Haematological parameters were determined using Haematology analyzer.

Biochemical Investigations:

Biochemical parameters were determined using auto-analyzer.

Histopathology:

Control and highest dose group animals will be initially subjected to histopathological investigations. If any abnormality found in the highest dose group than the low, then the mid dose group will also be examined. Organs will be collected from all animals and preserved in 10% buffered neutral formalin for 24 h and washed in running water for 24 h. The organ sliced 5 or 6µm sections and were dehydrated in an auto technicon and then cleared in benzene to remove absolute alcohol. Embedding was done by passing the cleared samples through three cups containing molten paraffin at 50°C and then in a cubical block of paraffin made by the "L" moulds. It was followed by microtome and the slides were stained with Haematoxylin-eosin red.

Statistical analysis:

Findings such as body weight changes, water and food consumption, hematology and blood chemistry were subjected to One-way ANOVA followed by dunnet t test using a computer software programme – Graph pad version 7. All data were summarized in tabular form, (Table-6 to 12)

RESULTS

Repeated Dose 28- day oral toxic study of KURUNTHOTTI KASHAYAM

Table 6: Body weight of wistar albino rats group exposed to *KURUNTHOTTI KASHAYAM*

DOSE	DAYS				
	1	7	14	21	28
CONTROL	235.2±18.46	236.5 ± 35.10	236.6 ± 45.60	238.7± 56.16	238.4 ± 66.15
LOW DOSE	248.2 ± 65.24	250.7 ± 66.28	254.6± 55.34	256 ±56.34	256.8± 35.36
MID DOSE	252.4± 18.34	253.3 ± 16.24	253.4 ± 14.12	255.2 ± 15.20	256.4 ± 54.10
HIGH DOSE	261.6± 62.24	261.4±42.22	262.4 ± 52.24	263 ± 54.28	264 ± 74.60
P value (p)*	NS	NS	NS	NS	NS

NS- Not Significant, **(p > 0.01),*(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 7: Water intake (ml/day) of Wistar albino rats group exposed to *KURUNTHOTTI KASHAYAM*

DOSE	DAYS				
	1	6	14	21	28
CONTROL	60.1 ± 8.72	60±1.52	60.2±1.40	61±1.32	61.4±1.62
LOW DOSE	65.1±1.21	65.6±4.22	66.6±1.02	65.2±2.06	66.4±1.20
MID DOSE	62.1±1.02	62.3±1.21	62.1±2.62	63.4±4.32	63.4±1.64
HIGH DOSE	64.1±1.81	64.2±1.32	64.4±1.14	64.6±1.62	65.8±2.02
P value (p)*	NS	NS	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 8: Food intake (gm/day) of Wistar albino rats group exposed to *KURUNTHOTTI KASHAYAM*

DOSE	DAYS				
	2	7	23	22	28
CONTROL	34±4.14	34.2±6.12	34.3±2.18	34.2±1.14	34±5.62
LOW DOSE	36.3±1.64	36.3±1.51	36.2±1.51	36.5±1.62	36.5±1.22
MID DOSE	34.1±2.12	34.2±3.50	34.2±2.14	34.2±2.16	35.2±1.64
HIGH DOSE	32.4±1.62	32.1±1.64	32.6±2.36	32.6±1.20	36.4±2.32
P value (p)*	NS	NS	NS	NS	NS

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test

Table 9: Haematological parameters of Wistar albino rats group exposed to *KURUNTHOTTI KASHAYAM*

Category	Control	Low dose	Mid dose	High dose	P value (p)*
Haemoglobin(g/dl)	13.4±0.71	13.30±0.14	13.4±0.13	13.72±0.13	N.S
Total WBC ($\times 10^3$ l)	09.41±0.22	09.32±0.22	09.34±0.22	09.30±1.10	N.S
Neutrophils (%)	21.13±0.60	21.02±0.52	22.11±1.42	22.02±2.71	N.S
lymphocyte (%)	82.10±1.26	82.12±1.42	83.10±2.44	83.20±2.54	N.S
Monocyte (%)	1.1±0.03	1.1±0.01	1.2±0.04	1.1±0.03	N.S
Eosinophil (%)	0.8±0.03	0.8±0.04	0.9±0.05	0.9±0.08	N.S
Platelets cells10^3/µl	900.17±3.18	902.11±4.62	902.11±2.20	902.22±2.64	N.S
Total RBC 10^6/ µl	9.32±0.11	9.47±0.33	9.50±0.64	9.60±0.46	N.S

PCV%	48.10±0.2	48.62±5.30	48.8±4.70	48.4±.71	N.S
MCHC g/dL	36.5±1.61	36.2±1.51	36.8±1.30	36.13±1.60	N.S
MCV fL(µm^3)	58.2±2.02	58.2±1.80	58.7±1.10	59.7±1.30	N.S

N.S- Not Significant, **(p > 0.01), *(p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 10 : Biochemical Parameters of of Wistar albino rats group exposed to *KURUNTHOTTI KASHAYAM*

BIOCHEMICAL PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
GLUCOSE (R) (mg/dl)	138.10±2.02	138.12±2.10	138.9±12.06	138.12±5.25	N.S
T.CHOLESTEROL(mg/dl)	140.14±5.10	140.15±5.20	142.40±1.68	143.21±1.10	N.S
TRIGLY(mg/dl)	74.15±1.82	74.11±1.32	74.15±1.22	76.16±1.21	N.S
LDL	78.6±2.13	78.7±2.05	78.10±1.03	78.40±01.32	NS
VLDL	14.2±1.52	14.20±2.41	14.02±1.32	14.04±12.15	NS
HDL	28.12±4.32	28.32±2.50	28.46±1.20	28.51±1.23	NS
Ratio 1(T.CHO/HDL)	3.73±1.16	3.72±1.80	3.73±1.32	3.74±2.33	NS
Ratio 2(LDL/HDL)	1.92±1.22	1.92±1.20	1.93±2.20	1.94±06.02	NS
Albumin (g/dL)	6.21±0.22	6.22±0.52	6.4±7.20	6.55±6.48	NS

NS- Not Significant, **(p > 0.01), * (p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 11: Renal function test of Wistar albino rats group exposed to *KURUNTHOTTI KASHAYAM*

PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
UREA (mg/dl)	14.50±0.29	14.50±0.29	14.46±1.18	14.42±1.22	N.S
CREATININE(mg/dl)	0.42±0.02	0.41±0.04	0.43±0.03	0.44±0.09	N.S
BUN(mg/dL)	19.1±0.02	19.10±0.34	19.6±0.42	19.26±1.02	NS
URIC ACID(mg/dl)	4.02±0.04	4.06±0.21	4.4±0.12	4.20±0.10	N.S

NS- Not Significant, **(p > 0.01), * (p >0.05) , n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test)

Table 12: Liver Function Test of of Wistar albino rats group exposed to *PATTAICHOORNAM*

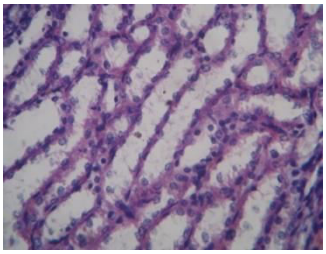
PARAMETERS	CONTROL	LOW DOSE	MID DOSE	HIGH DOSE	P Value (p)*
T BILIRUBIN(mg/dl).	0.08±0.01	0.08±0.03	0.08±0.03	0.08±0.01	N.S
SGOT/AST(U/L)	64.11±1.53	64.12±0.22	64.24±1.54	65.74±1.53	N.S
SGPT/ALT(U/L)	79.21±1.02	79.34±1.04	79.44±1.16	79.38±0.21	N.S
ALP(U/L)	137.11±2.21	137±2.20	139±1.24	140.03±6.02	N.S
T.PROTEIN(g/dL)	7.2.40±0.14	7.2±0.41	7.2±0.60	7.3±0.61	N.S

NS- Not Significant, **(p > 0.01), * (p >0.05), n = 10 values are mean ± S.D (One way ANOVA followed by Dunnett's test

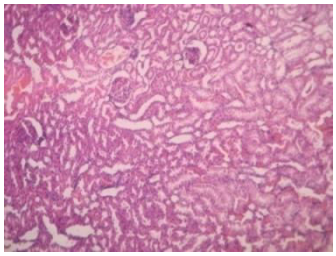
HISTO PATHOLOGY

CONTROL GROUP

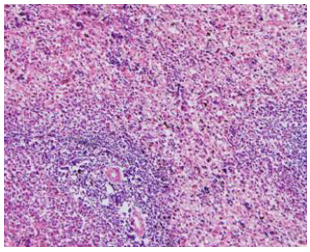
Kidney



Liver

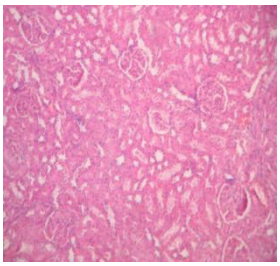


Spleen

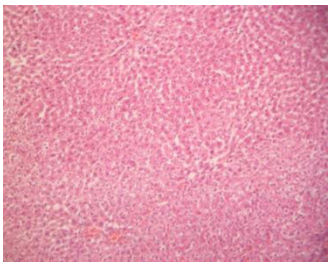


High dose

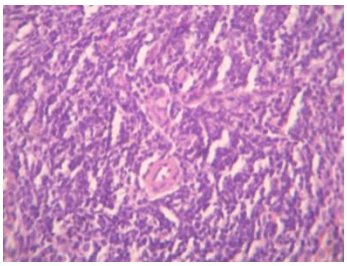
Kidney



Liver



Spleen



CONCLUSION:

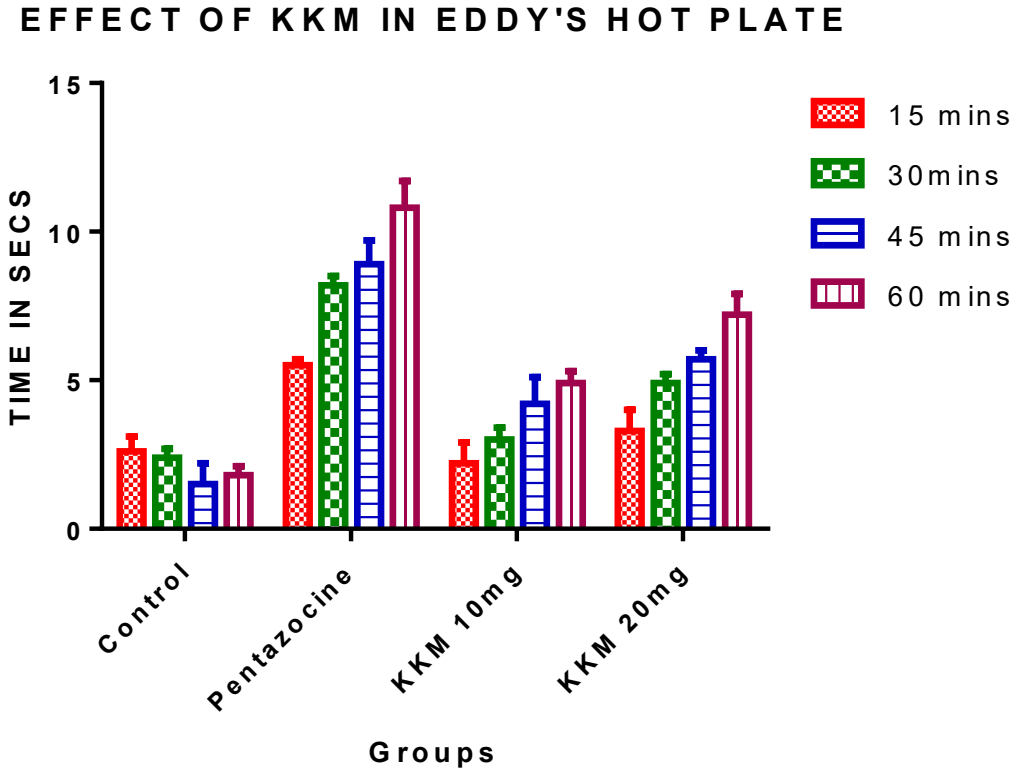
The acute toxicity study of the trial drug shown that Kurunthotti kashayam did not exhibit any significant toxicity at 2000 mg/kg body wt in acute toxicity study. It also did not exhibit any significant toxicity at 9 mg, 90 mg and 180 mg/kg bdwt in Sub acute toxicity studies. There were no significant changes in Serological and Hematological parameters in both the studies. Hence the trial drug is safe for administration.

Analgesic activity

Eddy's Hot plate method in rats

The hot plate assay method was employed for the purpose of preferential assessment of possible analgesic effects of Kurunthotti kashayam The analgesic drug, Pentazocine, was used for positive control group. In this experiment, four groups (n=6) of wister rats (200–250 g) were placed on a hot plate maintained at room temperature for 15 min. Food was withdrawn on the preceding night of the experiment. Group-1 normal control (0.5% CMC p.o.), and group-2 Pentazocine (30mg/kg, i.p.), whereas groups-3 and 4 animals received Kurunthotti kashayam (10 and 20 mg/kg, p. o respectively). Each animal was then individually placed gently on Eddy's hot plate at 55^{o}C. Latency to exhibit nociceptive responses such as licking paws or jumping off the hot plate, were determined 15, 30, 45 and 60 min after administration of the test drug or vehicle.

Groups	Dose Mg/ kg	Reaction time			
		15 mins	30mins	45 mins	60 mins
Control	10	2.6±.0.5	2.4±0.3	1.5±0.7	1.8±0.3
Pentazocine	30	5.5±0.2	8.2±0.3	8.9±0.8	10.8±0.9
Kurunthotti kashayam	10	2.2±0.7	3.0±0.4	4.2±0.9	4.9±0.4
Kurunthotti kashayam	20	3.3±0.7	4.9±0.3	5.7±0.3	7.2±0.7
N=6 ;Statistical analysis one way ANOVA followed by Dunnett t-test.					


EFFECT OF KKM IN EDDY'S HOT PLATE
TIME IN SECS
15
10
5
0
Control
Pentazocine
KKM 10mg
KKM 20mg
Groups
15 mins
30mins
45 mins
60 mins

Anti-inflammatory studies using Kurunthotti kashayam (KKM)

For the experiment, the animals were divided into 5 groups with 6 animals in each group.

- Group-I (control) received 3% gum acacia 10 ml/kg p.o.
- Group-II (Carageenan) received 0.1ml of 1% w/v suspension of carrageenan S.C
- Group-III (standard) received Indomethacin 40 mg/kg p.o.
- Group-1V(Test-1) received KKM 20mg/kg p.o.
- Group-V(Test-2) received KKM 40mg/kg p.o.

All the drugs were administered orally and the volume of medicaments kept constant at 10 ml/kg body weight of the animals it was administered orally to rats 1 hr before subcutaneous injection of carrageenan. After 1 hr 0.1ml of 1% w/v suspension of carrageenan was injected into sub-plantar region of the left hind paw to all the groups. The paw volume was measured at 1, 2, 3, 4, and 5 hr using Plethysmometer (Model 7150 UGO Basile, Italy) Edema was expressed as the mean increase in paw volume relative to control animals.

PAW EDEMA VOLUME

Group	Dose	Initial paw volume	Change in paw edema mm at different time intervals				
		0hr	1 hr	2hr	3hr	4hr	5hr
I	Control	1.20 ± 0.14	1.20±0.14	1.20±0.14	1.20±0.14	1.20±.14	1.20±0.14
II	Carrageenan	1.21± 0.17	1.91 ± 0.21	2.27 ± 0.02	2.37 ± 0.14	2.48 ± 0.18	2.62 ± 0.17
III	Indomethacin	1.01± 0.06	2.10 ± 0.26	1.56 ± 0.15	1.47 ± 0.05	1.34 ± 0.18	1.15 ± 0.16
IV	Low dose	1.44 ± 0.13	1.54 ± 0.32	1.64 ± 0.36	1.72 ± 0.64	1.53 ± 0.22	1.59 ± 0.32
V	High dose	1.22 ±0.44	1.92 ± 0.42	1.86 ± 0.54	1.66 ± 0.64	1.60 ± 0.28	1.30 ± 0.12

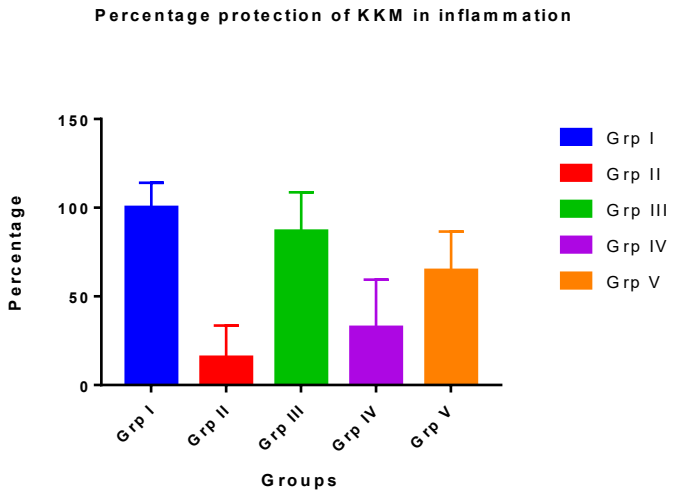
The paw volume up to the tribiotural articulation was measured at 0, 1, 2, 3, 4, 5 hrs

Group	Initial paw volume	5 hr in mm	Difference in paw volume	Percentage protection
I	1.20 ± 0.14	1.20±0.14	0.00	100
II	1.21± 0.17	2.62 ± 0.17	1.41	15.59
III	1.01± 0.06	1.15 ± 0.16	0.24	86.67
IV	1.44 ± 0.13	1.59 ± 0.32	0.15	32.42
V	1.32 ±0.44	1.30 ± 0.12	0.08	64.54

Percentage protection is calculated by the formulae: $(T_2 \text{---} T_1 / T_2)$ x 100

T_1----normal control

T_2 ----drug treated test



BIOSTATISTICS REPORTS

Improvement in subjects treated with Internal medicine (Group I)

The most popular non parametric statistical tool, namely, McNemar Test analysis has been employed to analyses the effectiveness with the help of a hypothesis.

IMPROVEMENT OF GROUP I SUBJECTS:

S. No	Clinical features	Before Treatment	After Treatment
		n%	n%
1.	Neck pain	20(100)	7(35)**
2.	Radiating pain in upper limbs	11(55)	1(5)**
3.	Stiffness of neck	8(40)	1(5)**
4.	Numbness	7(35)	1(5)**
5.	Giddiness	5(25)	1(5)*
6.	Tenderness	4(20)	2(10)*
7.	Movement restriction	1(5)	1(5)

McNemat test, C.I: 95%, *P<0.05; **P<0.01

Software: spss17 version

Number of cases: 20

Inference:

Since the p value is significant in all clinical features except Movement restriction. So there is significant reducing of clinical features among the patients for the treatment of Saganavatham (Cervical spondylosis). Hence it is concluded that the treatment was effective and **significant.**

Improvement in subjects treated with Internal & External Medicine only (Group II)

The most popular non parametric statistical tool, namely, McNemar Test analysis has been employed to analyses the effectiveness with the help of a hypothesis.

IMPROVE MENT OF GROUP II SUBJECTS:

S. No	Clinical features	Before Treatment	After Treatment
		n%	n%
1.	Neck pain	20(100)	3(15)**
2.	Radiating pain in upper limbs	10(50)	2(10)**
3.	Stiffness of neck	7(35)	1(5)*
4.	Numbness	7(35)	0(0)**
5.	Giddiness	4(20)	0(0)**
6.	Tenderness	5(25)	1(5)*
7.	Movement restriction	1(5)	0(0)*

McNemat test, C.I: 95%, *P<0.05; **P<0.01

Software: spss17 version

Number of cases: 20

Inference:

Since the p value is significant in all clinical features. So there is significant reducing of clinical features among the patients for the treatment of Saganavatham (Cervical spondylosis). Hence it is concluded that the treatment was effective and **significant.**

Improvement in subjects treated with Internal, External & Varmam therapy (Group III)

The most popular non parametric statistical tool, namely, McNemar Test analysis has been employed to analyses the effectiveness with the help of a hypothesis.

IMPROVE MENT OF GROUP III SUBJECTS:

S. No	Clinical features	Before Treatment	After Treatment
		n%	n%
1.	Neck pain	20(100)	1(5)**
2.	Radiating pain in upper limbs	10(50)	1(5)**
3.	Stiffness of neck	10(50)	1(5)**
4.	Numbness	7(35)	0(0)**
5.	Giddiness	5(25)	0(0)**
6.	Tenderness	4(20)	0(0)*
7.	Movement restriction	2(10)	0(0)*

McNemat test, C.I: 95%, *P<0.05; **P<0.01

Software: spss17 version

Number of cases: 20

Inference:

Since the p value is significant in all clinical features. So there is significant reducing of clinical features among the patients for the treatment of Saganavatham (Cervical spondylosis). Hence it is concluded that the treatment was effective and **significant.**

CLINICAL PROGNOSIS (ALL GROUPS)

The most popular non parametric statistical tool, namely, McNemar Test analysis has been employed to analyses the effectiveness with the help of a hypothesis.

S. No	Clinical features	Before Treatment	After Treatment
		n%	n%
1.	Neck pain	60(100)	11(18)**
2.	Radiating pain in upper limbs	31(52)	4(7)**
3.	Stiffness of neck	25(42)	3(5)**
4.	Numbness	21(35)	1(2)**
5.	Giddiness	14(23)	1(2)**
6.	Tenderness	13(22)	3(5)*
7.	Movement restriction	4(7)	1(2)*

McNemat test, C.I: 95%, *P<0.05; **P<0.01

Software: spss17 version

Number of cases: 60

Inference:

Since the p value is significant in all clinical features. So there is significant reducing of clinical features among the patients for the treatment of Saganavatham (Cervical spondylosis). Hence it is concluded that the treatment was effective and **significant.**

Pain assessment Score based on Visual analog scale

GROUP I SUBJECTS:

S.No.	Investigations	Before Treatment Mean±SD n= 20	After Treatment Mean±SD n= 20	P value
1	Visual analog scale	7.15±1.63	2.10±3.12	**<0.001**

C.I: 95%; Paired samples t test. Where p<0.001, p<0.05 represents statistically significant.

GROUP II SUBJECTS:

S.No.	Investigations	Before Treatment Mean±SD n= 20	After Treatment Mean±SD n= 20	P value
1	Visual analog scale	7.25±1.65	0.65±2.05	**<0.001**

C.I: 95%; Paired samples t test. Where p<0.001, p<0.05 represents statistically significant.

GROUP III SUBJECTS:

S.No.	Investigations	Before Treatment Mean±SD n= 20	After Treatment Mean±SD n= 20	P value
1	Visual analog scale	7.50±1.63	0.00±0.00	**<0.001**

C.I: 95%; Paired samples t test. Where p<0.001, p<0.05 represents statistically significant.

Since the P value is highly significant (<0.001) in 3 groups. So there is significant reducing Visual analog scale among the patients for the treatment of Saganavatham (Cervical spondylosis). Hence it is concluded that the treatment was effective **and significant.**

Physicochemical Evaluation

Project ID	**NRS/AS/0081/01/2018**
Name and Address of the Researcher	**Dr.Rasakumar** **Department of Special Medicine** **Govt Siddha Medical College, Chennai** **Tamilnadu, India**
Parameter Requested by the Customer for Analysis	**Physicochemical Analysis**
Sample Received	**Post**
Sample –ID	**KK**

Percentage Loss on Drying

10gm of test drug was accurately weighed in evaporating dish .The sample was dried at 105^{o}C for 5 hours and then weighed.

Percentage loss in drying = Loss of weight of sample/ Wt of the sample X 100

Determination of Total Ash

3 g of test drug was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ºC until it turns white in color which indicates absence of carbon. Percentage of total ash will be calculated with reference to the weight of air-dried drug.

Total Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of Acid Insoluble Ash

The ash obtained by total ash test will be boiled with 25 ml of dilute hydrochloric acid for 6mins. Then the insoluble matter is collected in crucible and will be washed with hot water and ignited to constant weight. Percentage of acid insoluble ash will be calculated with reference to the weight of air-dried ash.

Acid insoluble Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of Water Soluble Ash

The ash obtained by total ash test will be boiled with 25 ml of water for 5 mins. The insoluble matter is collected in crucible and will be washed with hot water, and ignite for 15mins at a temperature not exceeding 450ºC. Weight of the insoluble matter will be subtracted from the weight of the ash; the difference in weight

represents the water soluble ash. Calculate the percentage of water-soluble ash with reference to the air-dried drug.

Water Soluble Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of Alcohol Soluble Extractive

About 5 g of test sample will be macerated with 100 ml of Alcohol in a closed flask for twenty-four hours, shaking frequently during six hours and allowing to stand for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weigh. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried drug.

Alcohol sol extract = Weight of Extract/ Wt of the Sample taken X 100

Determination of Water Soluble Extractive

About 5 g of the test sample will be macerated with 100 ml of chloroform water in a closed flask for twenty-four hours, shaking frequently during six hours and allowing to stand and for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dry at 105ºC, to constant weight and weigh. Calculate the percentage of water-soluble extractive with reference to the air-dried drug.

Water soluble extract = Weight of Extract/ Wt of the Sample taken X 100

Determination of pH

About 5 g of test sample will be dissolved in 25ml of distilled water and filtered the resultant solution is allowed to stand for 30 mins and the subjected to pH evaluation

Final Test report

S.No	Parameter	Mean (n=3) SD
1.	***Loss on Drying at 105 °C (%)***	14.23 ± 1.68
2.	***Total Ash (%)***	10.17 ± 0.26
3.	***Acid insoluble Ash (%)***	11.73 ± 1.22
4.	***Water Soluble Ash (%)***	15.07 ± 1.72
5.	***Alcohol Soluble Extractive (%)***	23.9 ± 1.14

6.	***Water soluble Extractive (%)***	19.57 ± 1.75
7.	***PH***	5.1

Project Report

Project ID	**NRS/AS/0081/01/2018**
Source	**Dr.Rasakumar** **Department of Special Medicine** **Govt Siddha Medical College, Chennai** **Tamilnadu, India**
Purpose	**Phytochemical Analysis**
Sample –ID	**KK**

Extraction

Sample Extraction were carried out with water and the resulting extract was utilized for the phytochemical analysis

PHYTOCHEMICAL ANALYSIS

Test for alkaloids:

Mayer's Test: To the test sample, 2ml of mayer's reagent was added, a dull white precipitate revealed the presence of alkaloids.

Test for coumarins:

To the test sample, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow color.

Test for saponins:

To the test sample, 5 ml of water was added and the tube was shaken vigorously. Copious lather formation indicates the presence of Saponins.

Test for tannins:

To the test sample, ferric chloride was added, formation of a dark blue or greenish black color showed the presence of tannins.

Test for glycosides- Borntrager's Test

Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it. Pink colour indicates presence of glycosides.

Test for flavonoids:

To the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

Test for phenols:

Lead acetate test: To the test sample; 3 ml of 10% lead acetate solution was added. A bulky white precipitate indicated the presence of phenolic compounds.

Test for steroids:

To the test sample , 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence. It showed the presence of steroids.

Triterpenoids

Liebermann–Burchard test: To the chloroform solution, few drops of acetic anhydride was added then mixed well. 1 ml concentrated sulphuric acid was added from the sides of the test tube, appearance of red ring indicates the presence of triterpenoids.

Test for Cyanins

A. Aanthocyanin:

To the test sample, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100^{o}C. Formation of bluish green colour indicates the presence of anthocyanin.

Test for Carbohydrates - Benedict's test

To the test sample about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

TLC Analysis

Test sample was subjected to thin layer chromatography (TLC) as per conventional one dimensional ascending method using silica gel 60F254, 7X6 cm (Merck) were cut with ordinary household scissors. Plate markings were made with soft pencil. Micro pipette were used to spot the sample for TLC applied sample volume 10-micro liter by using pipette at distance of 1 cm at 5 tracks. In the twin trough chamber with different solvent system Toulene: Ethyl Acetate: Acetic Acid (1.5:1:0.5) After the run plates are dried and was observed using visible light Short-wave UV light 254nm and light long-wave UV light 365 nm

High Performance Thin Layer Chromatography Analysis

HPTLC method is a modern sophisticated and automated separation technique derived from TLC. Pre-coated HPTLC graded plates and auto sampler was used to achieve precision, sensitive, significant separation both qualitatively and quantitatively. High performance thin layer chromatography (HPTLC) is a valuable quality assessment tool for the evaluation of botanical materials efficiently and cost effectively. HPTLC method offers high degree of selectivity, sensitivity and rapidity combined with single-step sample preparation. In addition it is a reliable method for the quantitation of nano grams level of samples. Thus this method can be conveniently adopted for routine quality control analysis. It provides chromatographic fingerprint of phytochemicals which is suitable for confirming the identity and purity of medicinal plant raw materials.

Chromatogram Development

It was carried out in CAMAG Twin Trough chambers. Sample elution was carried out according to the adsorption capability of the component to be analysed. After elution, plates were taken out of the chamber and dried.

Scanning

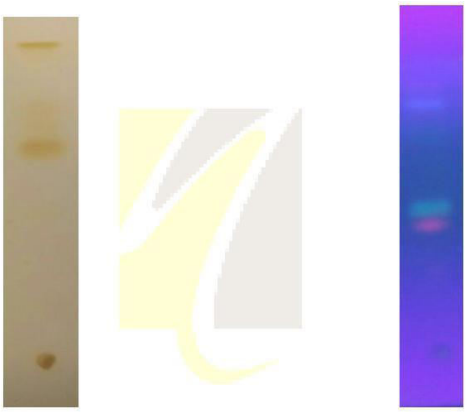
Plates were scanned under UV at 366nm. The data obtained from scanning were brought into integration through CAMAG software. Chromatographic finger print was developed for the detection of phytoconstituents present in each extract and Rf values were tabulated.

E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 - 42691289

Project ID	NRS/AS/0081/01/2018
Name and Address of the Researcher	Dr.Rasakumar Govt Siddha Medical College, Chennai Tamil Nadu, India
Parameter Requested by the Customer for Analysis	HPTLC Analysis
Sample Received	Post
Sample –ID	KK
Description of the Sample	Solid
Method of Analysis Instrument TLC Plate Mobile Phase Extraction Solvent	 CAMAG TLC SCANNER III Aluminium Coated Silica Gel – Merck Toulene: Ethyl Acetate: Acetic Acid (1.5:1:0.5) Acetone
Analysis Type	Third Party Analysis
Date of Analysis	30/01/2018
Result of Analysis	Test Report Attached

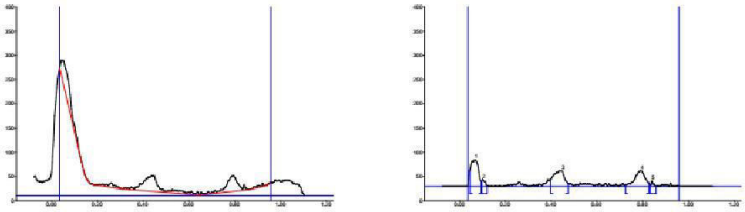
E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 - 42691289

TLC Analysis at 254 nm **TLC Analysis at 366 nm**



E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 - 42691289

HPTLC finger printing of Sample KK



Peak Table

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	0.04	34.2	0.07	55.8	37.53	0.10	10.6	1383.5	35.51
2	0.10	11.4	0.10	15.1	10.17	0.12	0.0	156.2	4.01
3	0.40	14.3	0.45	33.0	22.21	0.48	6.3	1171.1	30.06
4	0.73	4.0	0.79	33.1	22.24	0.83	7.2	1104.8	28.35
5	0.84	1.6	0.84	11.7	7.85	0.86	0.1	80.9	2.08

REPORT

HPTLC finger printing analysis of the sample KK reveals the presence of five prominent peaks corresponds to presence of five versatile phytocomponents present with in it. Rf value of the peaks ranges from 0.04 to 0.84. Further the peak 1 occupies the major percentage of area of 37.53 % which denotes the abundant existence of such compound. Followed by this peak 4 and 3 occupies the percentage area of 22.24 and 22.21%.

AFLATOXIN ASSAY BY TLC (B1,B2,G1,G2)

Standard

Aflatoxin B1

Aflatoxin B2

Aflatoxin G1

Aflatoxin G2

Solvent

Standard samples was dissolved in a mixture of chloroform and acetonitrile (9.8 : 0.2) to obtain a solution having concentrations of 0.5 µg per ml each of aflatoxin B1 and aflatoxin G1 and 0.1 µg per ml each of aflatoxin B2 and aflatoxin G2.

Test solution: Concentration 1 µg per ml

Procedure

Standard aflatoxin was applied on to the surface to pre coated TLC plate in the volume of 2.5 µL, 5 µL, 7.5 µL and 10 µL. Similarly the test sample was placed and Allow the spots to dry and develop the chromatogram in an unsaturated chamber containing a solvent system consisting of a mixture of chloroform, acetone and isopropyl alcohol (85: 10: 5) until the solvent front has moved not less than 15 cm from the origin. Remove the plate from the developing chamber, mark the solvent from and allow the plate to air-dry. Locate the spots on the plate by examination under UV light at 365 nm.

HEAVY METAL ANALYSIS BY AAS

Standard: Hg, As, Pb and Cd – Sigma

Methodology

Atomic Absorption Spectrometry (AAS) is a very common and reliable technique for detecting metals and metalloids in environmental samples. The total heavy metal content of the sample KN was performed by Atomic Absorption Spectrometry (AAS) Model AA 240 Series. In order to determination the heavy metals such as mercury, arsenic, lead and cadmium concentrations in the test sample.

Sample Digestion

Test sample digested with 1mol/L HCl for determination of arsenic and mercury. Similarly for the determination of lead and cadmium the sample were digested with 1mol/L of HNO3.

Standard reparation

As & Hg- 100 ppm sample in 1mol/L HCl

Cd & Pb- 100 ppm sample in 1mol/L HNO_3

TLC Analysis

Test sample was subjected to thin layer chromatography (TLC) as per conventional one dimensional ascending method using silica gel 60F254, 7X6 cm (Merck) were cut with ordinary household scissors. Plate markings were made with soft pencil. Micro pipette were used to spot the sample for TLC applied sample volume 10-micro liter by using pipette at distance of 1 cm at 5 tracks. In the twin trough chamber with different solvent system Toulene: Ethyl Acetate: Acetic Acid (1.5:1:0.5) After the run plates are dried and was observed using visible light Short-wave UV light 254nm and light long-wave UV light 365 nm

High Performance Thin Layer Chromatography Analysis

HPTLC method is a modern sophisticated and automated separation technique derived from TLC. Pre-coated HPTLC graded plates and auto sampler was used to achieve precision, sensitive, significant separation both qualitatively and quantitatively. High performance thin layer chromatography (HPTLC) is a valuable quality assessment tool for the evaluation of botanical materials efficiently and cost effectively. HPTLC method offers high degree of selectivity, sensitivity and rapidity combined with single-step sample preparation. In addition it is a reliable method for the quantitation of nano grams level of samples. Thus this method can be conveniently adopted for routine quality control analysis. It provides chromatographic fingerprint of phytochemicals which is suitable for confirming the identity and purity of medicinal plant raw materials.

Chromatogram Development

It was carried out in CAMAG Twin Trough chambers. Sample elution was carried out according to the adsorption capability of the component to be analysed. After elution, plates were taken out of the chamber and dried.

Scanning

Plates were scanned under UV at 366nm. The data obtained from scanning were brought into integration through CAMAG software. Chromatographic finger print was developed for the detection of phytoconstituents present in each extract and Rf values were tabulated.

PESTICIDE RESIDUE ANALYSIS

Extraction

About 10 g of test substance were extracted with 100 ml of acetone and followed by homogenization for brief period. Further filtration was allowed and subsequent addition of acetone to the test mixture. Heating of test sample was performed using a rotary evaporator at a temperature not exceeding 40ºC until the solvent has almost completely evaporated. To the residue add a few milliliters of toluene R and heat again until the acetone is completely removed. Resultant residue will be dissolved using toluene and filtered through membrane filter.

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

AN OPEN COMPARATIVE CLINICAL TRIAL ON SAGANAVATHAM (CERVICAL SPONDYLOSIS) WITH THE EVALUATION OF SIDDHA TRIAL DRUG "KURUNTHOTTI KASAYAM" (INTERNAL) "AZHINJIL THAILAM" (EXTERNAL) AND 'VARMAM THERAPY'

FORM l - SCREENING AND SELECTION PROFORMA

1. OP NO: .....

2. NAME: …….

3. AGE: …… 4.GENDER: …….....

5. OCCUPATION: …….. 6.INCOME: ……

7. ADDRESS: ……

……

……

8. CONTACT NO: ……

INCLUSION CRITERIA

- Neck stiffness
- Pain in the nape of the neck
- Radiating pain to the upper limbs up to the tip of the fingers
- With or without numbness in the upper limbs
- Age: Between18- 60 years
- Sex : Both male and female
- Limitations of movements
- Willing to sign the consent form

EXCLUSION CRITERIA

(Clinical history)

- Atlanto axial subluxation
- Scalene syndrome
- Adhesive capsulitis
- Supraspinatus tendinitis
- Congenital deformities of spine like Torticolis, spina bifida & scoliosis
- Sero Negative Spondylarthropathy like Ankylosing spondylitis, Polyarthritis etc
- Syringomyelia
- Cardiac diseases
- Pregnant women and lactating mothers
- Neoplasms
- Meningitis
- Wry neck
- TB in cervical spine(caries spine)
- Patients with any other serious systemic illness

ADMITTED TO TRIAL:

YES **NO**

If yes, **OPD /IPD**

Date:

Station:

Signature of the Guide: Signature of the Investigator:

GOVERNMENT SIDDHA MEDICAL COLLEGE

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CHENNAI – 600 106

AN OPEN COMPARATIVE CLINICAL TRIAL ON SAGANAVATHAM (CERVICAL SPONDYLOSIS) WITH THE EVALUATION OF SIDDHA TRIAL DRUG "KURUNTHOTTI KASAYAM" (INTERNAL) "AZHINJIL THAILAM" (EXTERNAL) AND 'VARMAM THERAPY'

FORM II -HISTORY TAKING PROFORMA

1. SERIAL NO OF THE CASE: ……. 2.OP/IP NO:

.....

3. NAME: …… 4. AGE: …….. 5. GENDER:

……..

5. OCCUPATION: …… 6. INCOME:

……..

7.COMPLAINTS & DURATION:

8. CHIEF COMPLAINTS WITH DURATION

HISTORY OF PRESENT ILLNESS

1. Onset of disease	**:**	Acute	Insidious
2. Duration of disease	**:**		
3. Treatment given so far	**:**	Ayurvedic medicine Modern Medicine Unani Homeopathy	

8.PERSONAL HISTORY:

PERSONAL HABITS	YES	NO	IF YES, SPECIFY DURATION/QUANTITY
Smoking			
Tobacco Chewing			
Alcoholism			
Narcotic drugs			

9. HISTORY OF PREVIOUS ILLNESS/PELVIC SURGERY

10. DIETARY HABIT:

1.Vegetarian

2.Non-vegetarian

11. FAMILY HISTORY:

Whether this problem runs in family?

1. Yes 2.No

If yes, mention the relationship of affected person(s) ----------

History of previous investigations if any ----------

Date: Station:

Signature of the Guide: Signature of the Investigator:

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN COMPARATIVE CLINICAL TRIAL ON SAGANAVATHAM (CERVICAL SPONDYLOSIS) WITH THE EVALUATION OF SIDDHA TRIAL DRUG "KURUNTHOTTI KASAYAM" (INTERNAL) "AZHINJIL THAILAM" (EXTERNAL) AND 'VARMAM THERAPY'

FORM III

CLINICAL ASSESSMENT ON ENROLLMENT AND ON VISITS

1. SI NO:------ 2 OP /IP NO: ---------- 3. NAME :----------

4. RELIGION : H / C / M / O

5. AGE/GENDER :------- 6. OCCUPATION :----------
7. SOCIAL STATUS : ---------- 8.CONTACT NUM:----------

SIDDHA SYSTEM OF EXAMINATION

1. THEGI (BODY CONSTITUTION):

1. Vatha udal ☐
2. Pitha udal ☐
3. Kaba udal ☐
4. Thontha udal ☐

2. NILAM (LAND WHERE THE PATIENT LIVED MOST):

1. Kurinji ☐

2. Mullai ☐

3. Marutham ☐

4. Neithal ☐

5. Paalai ☐

3. KAALAM:

1. Kaar kaalam (Aavani-Puratasi) ☐

2. Koothir kaalam (Ippasi-Kaarthigai) ☐

3. Munpani kaalam (Maargazhi-Tai) ☐

4. Pinpani kaalam (Maasi-Panguni) ☐

5. Ilavenil kaalam (Chithirai-Vaigasi) ☐

6. Muthuvenil kaalam (Aani-Aadi) ☐

4. GUNAM:

1. Sathuvam ☐

2. Rasatham ☐

3. Thamasam ☐

5. PORIPULANGAL (SENSORY ORGANS):

NormalAffected

1. Mei ☐.....☐.....

2. Vaai (Naaku) ☐ ☐

.....

3. Kan ☐ ☐

.....

4. Mookku ☐ ☐

.....

5. Sevi ☐ ☐

.....

6. KANMENDRIYAM (MOTOR ORGANS) :

NormalAffected

1. Vaai ☐ ☐

.....

2. Kaal ☐ ☐

.....

3. Kai ☐ ☐

.....

4. Eruvaai ☐ ☐

.....

5. Karuvaai ☐ ☐

.....

7. KOSANGAL (SHEATH):

NormalAffected

1. Annamaya kosam . ☐ ☐

.....

2. Pranamaya kosam.....☐.....☐.....

3. Manomaya kosam.....☐... . .☐.....

4. Vignanamaya kosam ☐.....☐.....

5. Anandhamaya kosam ☐.....☐.....

8. UYIR THATHUKKAL (THREE HUMOURS):

8a.VALI: Normal Affected

1. Praanan ☐ ☐

.....

2. Abaanan ☐ ☐

.....

3. Viyaanan ☐ ☐

.....

4. Uthaanan ☐ ☐

.....

5. Samaanan ☐ ☐

.....

6. Naagan ☐ ☐

.....

7. Koorman ☐ ☐

.....

8. Kirukaran ☐ ☐

.....

9. Devathathan ☐ ☐

.....

10. Dhananjayan ☐ ☐.

.....

8b. AZHAL: Normal Affected

1. Analam ☐ ☐

.....

2. Ranjagam ☐ ☐

.....

3. Saathagam ☐ ☐

.....

4. Aalosagam ☐ ☐

.....

5. Praasagam ☐ ☐

.....

8c.IYAM: Normal Affected

1. Avalambagam ☐ ☐

.....

2. Kilethagam ☐ ☐

.....

3. Pothagam ☐ ☐

.....

4. Tharpagam ☐ ☐

.....

5. Santhigam ☐ ☐

.....

9. EN VAGAI THERVU (EIGHT FOLDS OF EXAMINATION):

1.Naadi: …….....

2.Parisam: …….....

3.Naa : .....…….....

4.Niram : .....…….....

5.Mozhi: .....…….....

6.Vizhi : .....

7.Malam : .....

8. Moothiram: …….

8a.Neerkuri:

Niram : 1.Whitish ☐ 2. Yellowish ☐

3.Straw coloured ☐ 4. Crystal clear ☐

Edai: 1.Present ☐ 2.Absent ☐

Manam : 1.Nil ☐ 2.Reduced ☐ 3. Increased ☐

Nurai: 1. Normal ☐ 2. Increased ☐ 3. Decreased ☐

Enjal:

8b: Neerkuri (Oil –in urine sign):

Vatha Neer ☐ Pitha Neer ☐ Kaba Neer ☐

10. SEVEN UDAL THAATHUKKAL (SEVEN SOMATIC COMPONENTS):

NormalAffected

1. Saaram ☐ ☐

.....

2. Senneer ☐ ☐

.....

3. Oon ☐ ☐

.....

4. Kozhuppu ☐ ☐

☐

.....

5. Enbu ☐

..... ☐ ☐Moolai

.....

7. Sukkilam / Suronitham ☐ ☐

GENERAL EXAMINATION:

1. Body weight [Kg] :
2. Height [cm] :
3. Body Temperature [F] :
4. Blood Pressure (mmHg) :
5. Pulse Rate /min. :
6. Heart Rate / min. :
7. Respiratory Rate /min. :

		Yes	**No**
8. Pallor	:	☐	☐
9. Jaundice	:	☐	☐
10. Clubbing	:	☐	☐
11. Cyanosis	:	☐	☐
12. Pedal Oedema	:	☐	☐
13. Lymphadenopathy	:	☐	☐
14. Jugular venous pulsation	:	☐	☐

VITAL ORGAN EXAMINATION:

	Normal	**Abnormal**
1. Heart	☐	☐
2. Lungs	☐	☐
3. Brain	☐	☐
4. Liver	☐	☐
5. Kidney	☐	☐
6. Spleen	☐	☐
7. Stomach	☐	☐

SYSTEMIC EXAMINATION:

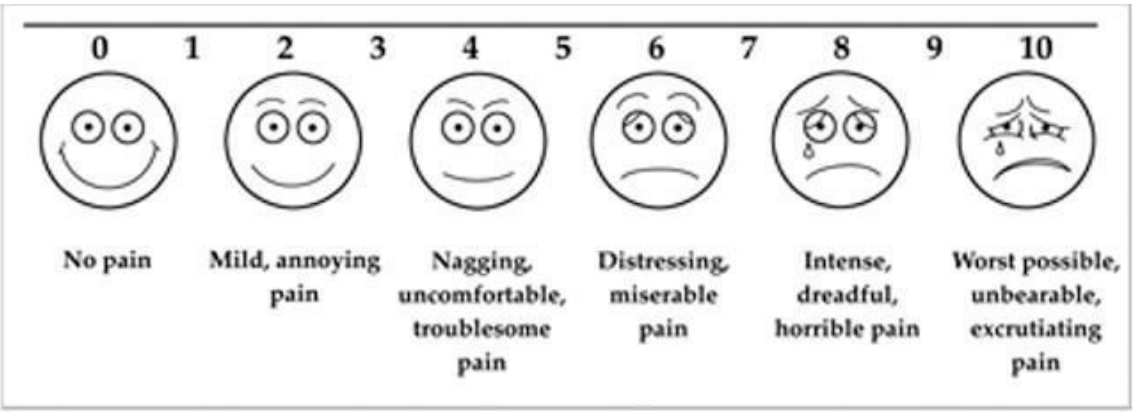
	Normal	Abnormal
1. Cardio-vascular system	☐	☐
2. Respiratory system	☐	☐
3. Gastro intestinal system	☐	☐
4. Central nervous system	☐	☐
5. Genital urinary system	☐	☐
6. Endocrine system	☐	☐

CLINICAL ASSESSMENT:

COMPLAINTS	0^{th} day	7^{th} day	14^{th} day	21^{st} day
Pain in neck				
Radiating pain in Upper limbs				
Stiffness of neck				
Numbness				
Giddiness				
Tenderness				
Restriction of movements				

PAIN ASSESMENT:

VISUAL ANALOGUE SCALE;



Bsfeore Treatment: After Treatment:

Difference (Change in VAS points):

CLINICAL EXAMINATION

I. INSPECTION

	0^{th} day	7^{th} day	14^{th} day	21^{st} day	28^{th} day	35^{th} day	42^{nd} day	49^{th} day
ATTITUDE								
MUSCLE WASTING								
SWELLING								

II PALPATION:

	0^{th} day	7^{th} day	14^{th} day	21^{st} day	28^{th} day	35^{th} day	42^{nd} day	49^{th} day
Tenderness								
Muscle spasm								
Local heat								
Local lymph adenopathy								
Pitting oedema								
Joint								

stiffness								

III. MOVEMENTS:

	0^{th} day	7^{th} day	14^{th} day	21^{st} day	28^{th} day	35^{th} day	42^{nd} day	49^{th} day
Stiffness								
Rotation								
Flexion								
Extension								
Lateral bending								
Restriction of movements:								

Date :
Station:
Signature of the Investigator:
Signature of the Lecturer: Signature of the HOD

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

POST- GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM

AN OPEN COMPARATIVE CLINICAL TRIAL ON SAGANAVATHAM (CERVICAL SPONDYLOSIS) WITH THE EVALUATION OF SIDDHA TRIAL DRUG "KURUNTHOTTI KASAYAM" (INTERNAL) "AZHINJIL THAILAM" (EXTERNAL) AND 'VARMAM THERAPY'

FORM IV : LABORATORY INVESTIGATIONS

PROFORMA

1. SERIAL NO OF THE CASE: ……

2.OP / IP NO: .....

3. NAME: …… 4.AGE: …… 5.GENDER: .....

A) BLOOD INVESTIGATIONS:

BLOOD INVESTIGATIONS		BEFORE TREATMENT	AFTER TREATMENT
Hb (gm/dL)			
T.RBC (millions cells / Cu.mm)			
ESR (mm)	½ hr.		
	1 hr.		
T.WBC (Cells / Cu.mm)			
Differential Count (%)	Polymorphs		
	Lymphocytes		
	Monocytes		
	Eosinophils		
	Basophils		

BLOOD INVESTIGATIONS		BEFORE TREATMENT	AFTER TREATMENT
Blood glucose (mg/dl)	**Random**		
	PP		
Serum Calcium			
Renal Function Test	**Blood urea**		
	Serum creatinine		

B) URINE INVESTIGATIONS:

URINE INVESTIGATIONS	BEFORE TREATMENT	AFTER TREATMENT
Albumin		
Sugar		
Deposits		
Urine Culture		

C) RADIOLOGICAL EXAMINATIONS:

X RAY – Cervical Spine AP / LAT view

Date:

Station:

Signature of the Guide: Signature of the Investigator:

GOVERNMENT SIDDHA MEDICAL COLLEGE

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CHENNAI – 600 106

CERTIFICATE OF CONSENT

STUDY TITLE:

AN OPEN COMPARATIVE CLINICAL TRIAL ON SAGANAVATHAM (CERVICAL SPONDYLOSIS) WITH THE EVALUATION OF SIDDHA TRIAL DRUG "KURUNTHOTTI KASAYAM" (INTERNAL) "AZHINJIL THAILAM" (EXTERNAL) AND 'VARMAM THERAPY'

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any question I have asked has been answered to my satisfaction.

I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my further medical care".

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant Signature of the investigator

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely."

Date:

Signature of a witness

(Selected by the participant bearing no connection with the survey team)

Left thumb Impression of the participant

ஒப்புதல் படிவம்

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106
அறிஞர் அண்ணா மருத்துவமனை, சென்னை

சகன வாதத்திற்கான சித்த மருந்தின் குறுந்தோட்டி கசாயம் மற்றும்
அழிஞ்சில் **தைலம்** மற்றும் வர்ம சிகிச்சை பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் இந்த ஆய்வு குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி: **கையொப்பம்:**

இடம்: **பெயர் :**

நோயாளியின் ஒப்புதல்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும், தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும், அதனை பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது, காரணம் எதுவும் கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து என்னை விடுவித்து கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன். நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு சகன வாத நோய்க்கான **குறுந்தோட்டி கசாயம்** (உள் மருந்து) மற்றும் அழிஞ்சில் **தைலம்** (வெளி மருந்து) மற்றும் **வர்ம சிகிச்சை** மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: **கையொப்பம்**

இடம்: **பெயர்**

தேதி: **சாட்சிக்காரர் கையொப்பம்**

இடம்: **பெயர்**

உறவுமுறை

GOVERNMENT SIDDHA MEDICAL COLLEGE,

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

AN OPEN COMPARATIVE CLINICAL TRIAL ON SAGANAVATHAM (CERVICAL SPONDYLOSIS) WITH THE EVALUATION OF SIDDHA TRIAL DRUG "KURUNTHOTTI KASAYAM" (INTERNAL) "AZHINJIL THAILAM" (EXTERNAL) AND 'VARMAM THERAPY'

FORM VI - WITHDRAWAL FORM

SI NO:

OP / IP NO:

NAME:

AGE / GENDER :

DATE OF TRIAL COMMENCEMENT:

DATE OF WITHDRAWAL FROM TRIAL:

REASONS FOR WITHDRAWAL:

- Long absence at reporting : Yes/ No
- Irregular treatment: Yes/ No
- Shift of locality : Yes/No
- Increase in severity of symptoms: Yes/No
- Development of severe adverse drug reactions: Yes/No

Date:

Station:

Signature of the Guide: Signature of the Investigator:

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CHENNAI – 600 106

AN OPEN COMPARATIVE CLINICAL TRIAL ON SAGANAVATHAM (CERVICAL SPONDYLOSIS) WITH THE EVALUATION OF SIDDHA TRIAL DRUG "KURUNTHOTTI KASAYAM" (INTERNAL) "AZHINJIL THAILAM" (EXTERNAL) AND 'VARMAM THERAPY'

FORM VII – PATIENT INFORMATION SHEET

Name of Investigator: Dr. R. RASAKUMAR

Name of the college: Govt. Siddha Medical College

Arumbakkam

Chennai-106.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I, Dr.R.RASAKUMAR studying M.D (Siddha) at Govt.Siddha Medical College, Chennai, is doing a clinical trial on "Saganavadham(Cervical spondylosis)". It is becoming a most common disease, occurring throughout the world. In this regard, I am in need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine 'KURUNTHOTTI KASHAYAM" (Internal medicine) 30 – 60 ml bid for 21 days.

The information I am collecting in this study will remain between you and the Co- investigator (myself). I will ask you few questions through a questionnaire. I will not write your name on this form. I will use a code instead.

The questionnaire will take approximately 20 minutes of your time.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact R. RASAKUMAR, PG Scholar cum investigator of this study, attached to Govt. Siddha Medical College, Chennai-106. You can also contact the Member-secretary of Ethics committee, Govt.Siddha Medical College, Chennai.

Contact No: 9843172369
Email: rasakumar29@gmail.com

Date:
Place:

Signature of the Guide:

Signature of the Investigator:

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106
அறிஞர் அண்ணா மருத்துவமனை, சென்னை

சகன வாதத்திற்கான சித்த மருந்தின் குறுந்தோட்டி கசாயம் மற்றும் அழிஞ்சில் தைலம்
பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

ஆராய்ச்சியாளர் பெயர்: மருத்துவர். இரா. இராசகுமார்

நிறுவனத்தின் பெயர் : அரசு சித்த மருத்துவக் கல்லூரி
அரும்பாக்கம்,
சென்னை-106

அரசு சித்த மருத்துவக் கல்லூரியில் பட்ட மேற்படிப்பு பயின்று வரும் நான் மருத்துவர். இரா. இராசாகுமார், **சகன வாதம்** என்னும் நோயில் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

இது பரவக் கூடிய நோய் அல்ல.

இந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகளைக் கேட்கவும், தேவையான ஆய்வகப் பரிசோதனைக்கு தங்களை உட்படுத்தவும் உள்ளேன்.

இந்த ஆராய்ச்சிக்கு தாங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக **குறுந்தோட்டி கசாயம்** 30-60 மிலி 2 வேளை(காலை, மாலை) உணவுக்கு பின் 21 நாட்கள் உட்கொள்ள வேண்டும்.. வெளி நோயாளர்கள் 7 நாட்களுக்கு ஒருமுறை மருத்துவமனைக்கு வர வேண்டும்.

இந்த மருந்து சிறப்பாக **சகன வாதத்திற்கு** அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது.

இந்த ஆராய்ச்சியில் தங்களை அனுமதித்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் ஆராய்ச்சியில் இருந்து விளகிக் கொள்ள உரிமை உள்ளது.

இந்த ஆராய்ச்சி சம்பந்தமாக நோயின் தன்மை பற்றியும் மற்ற விபரங்களுக்கும் ஆராய்ச்சியாளரான மருத்துவர்: இரா. இராசகுமார் (பட்ட மேற் படிப்பாளர் சிறப்பு மருத்துவ துறை) அவர்களை எந்த நேரத்திலும் தொடர்பு கொள்ளலாம் கைப்பேசி எண்: 9843172369

மேலும் இந்த ஆராய்ச்சிக்கு தக்க அனுமதிச் சான்று (IEC) பெறப்பட்டுள்ளது.

மேலும் உணவு முறையில் மருத்துவரால் கூறப்படும் பத்தியம் காக்குமாறு அறிவுறுத்த படுகிறது.

இது சம்பந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதிஅளிக்கிறேன்.

இதில் பயணப்படி முதலிய எந்த உதவித் தொகையும் வழங்கப் பட மாட்டாது.

இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் அறிஞர் அண்ணா மருத்துவமனையில்,தக்க சிகிச்சை அளிக்கப்படும்

தேதி:

இடம்:

துறைத்தலைவர் கையொப்பம்:

ஆராய்ச்சியாளர் கையொப்பம்:

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

AN OPEN COMPARATIVE CLINICAL TRIAL ON SAGANAVATHAM (CERVICAL SPONDYLOSIS) WITH THE EVALUATION OF SIDDHA TRIAL DRUG "KURUNTHOTTI KASAYAM" (INTERNAL) "AZHINJIL THAILAM" (EXTERNAL) AND 'VARMAM THERAPY'

FORM IV D
DIETARY ADVICE FORM

சேர்க்க கூடிய உணவுகள்:

- **காய்கள்**:கத்தரிபிஞ்சு,முருங்கைபிஞ்சு,,அவரைபிஞ்சு,
  ஆகியவை சேர்க்க வேண்டும்.

- **கீரைகள்**:கரிசாலை,பொன்னாங்கண்ணி,மணத்தக்காளி,
  முருங்கைகீரை,பசலைகீரை,சிறுகீரை, கறிவேப்பிலை ஆகியவை சேர்க்க வேண்டும்.

- **பழங்கள்**:மாதுளை,ஆப்பிள்,வாழை,பேரீச்சை,அத்தி,
  திராட்சை,கொய்யா,ஆரஞ்சு,எலுமிச்சை, நாவல்,தக்காளி,ஆகியவை சேர்க்க வேண்டும்.

- **தானியங்கள்**:கோதுமை,ஓட்ஸ்,சோயாபீன்ஸ்,பட்டாணி,
  கொண்டைகடலை,எள்,பாதாம் ஆகியவை
  சேர்க்க வேண்டும்.

- **அசைவம்**:வெள்ளாட்டுகறி,ஈரல்,எலும்புமஜ்ஜை,
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சேர்க்க கூடாதவைகள்:

- மந்தப் பொருள்
- உருளைக் கிழங்கு.
- அகத்திக்கீரை.
- புளிப்பு.
- புகையிலை
- மது அருந்துதல்

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